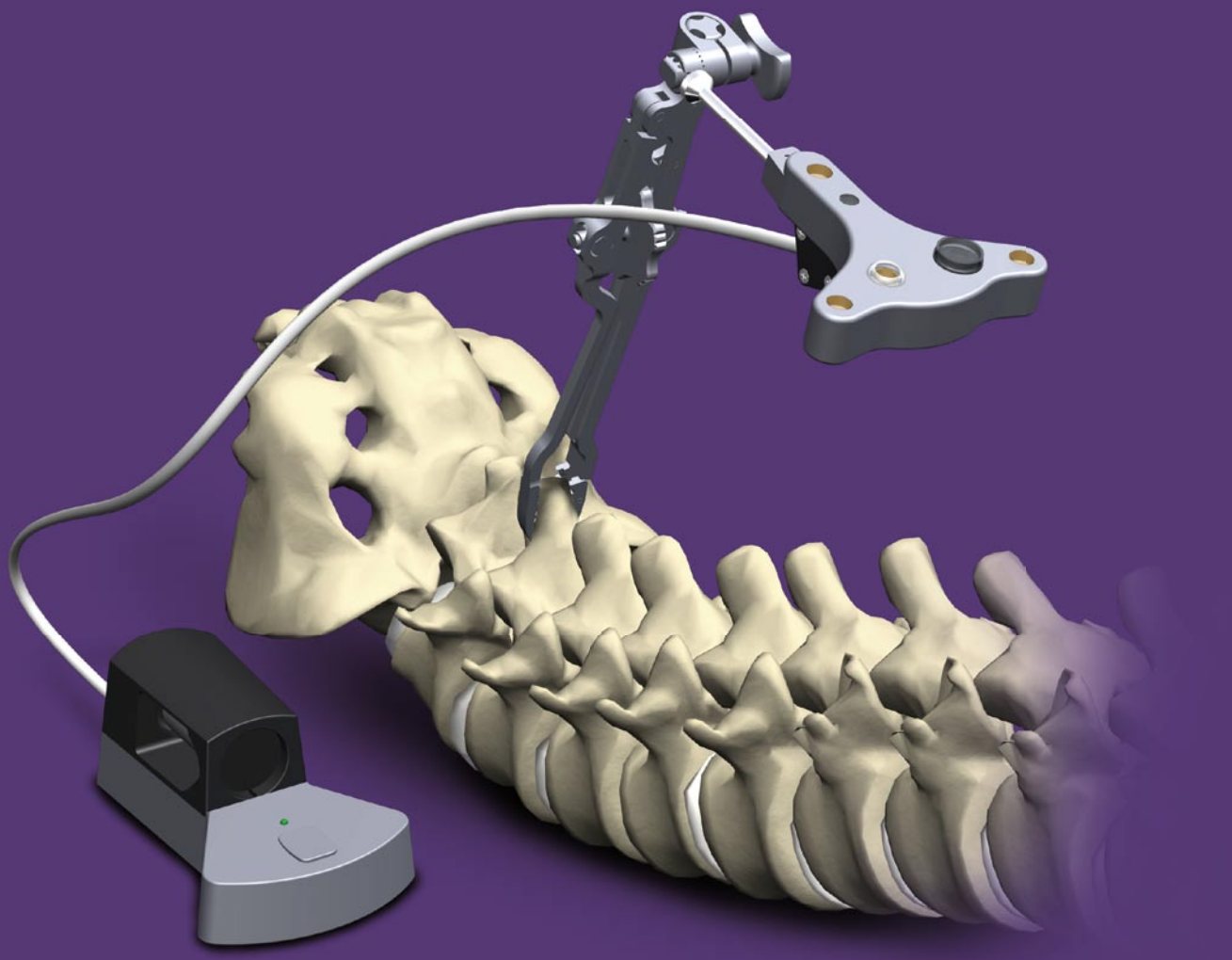
stryker®

SpineMap® 3D User Manual

SpineMap® 3D Navigation Software 2.0



Introduction/Description of Symbols

This user manual provides general instructions on the use of the Stryker Navigation System software for image guided computer assisted orthopaedic surgery.

It contains information on the planning, navigation, functions and the general concept of operations for SpineMap 3-D Navigation.

Symbol used in this document	
Symbol	Description
⚠	Marks a warning or caution message

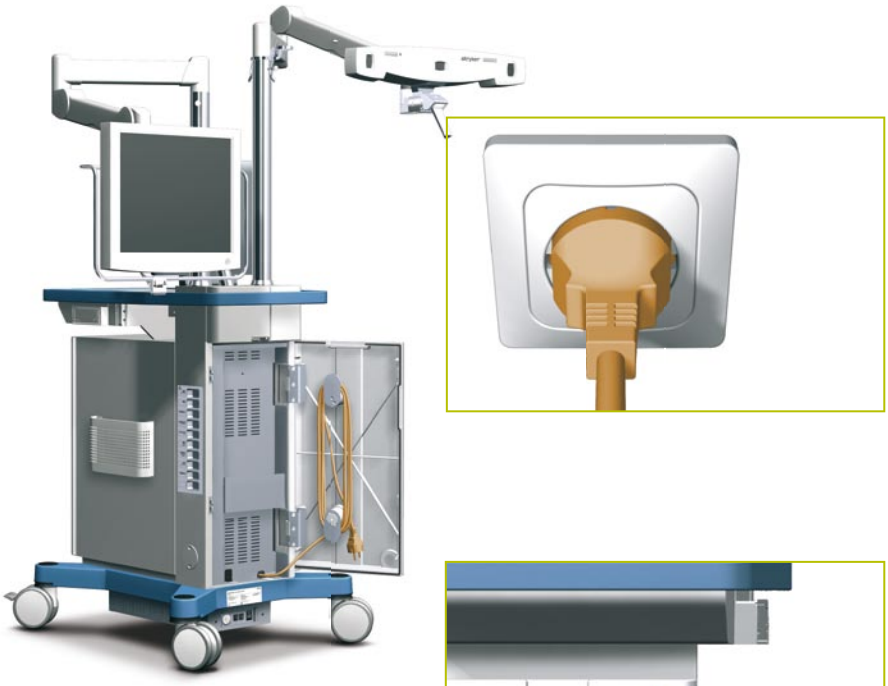
Symbols used in the software	
Symbol	Description
ℹ	Marks an information message
⊗	Marks an error message
⚠	Marks a warning message

	User Group	Medical Professional (surgeon/resident, radiologist, nurse/professional caregiver)
	Refer to documentation	For the required safety information and contraindications, please refer to the SpineMap 3-D 2.0 Safety Information and the Imaging Protocol supplied with the software package, as well as the instructions for use supplied with the system components. For detailed instructions and the required safety information related to the Anchoring systems, Anchoring Pins, Point and Vector Calibration Devices, refer to the instructions for use supplied with these instruments. For information related to the use of conventional instrumentation, please refer to the user documentation supplied with each company's conventional instrumentation.
As with any technical guide, the surgeon should consider the particular condition of the patient and perform the necessary adjustments if required. Safety and caution should always be utilized before proceeding.		

Table of Contents

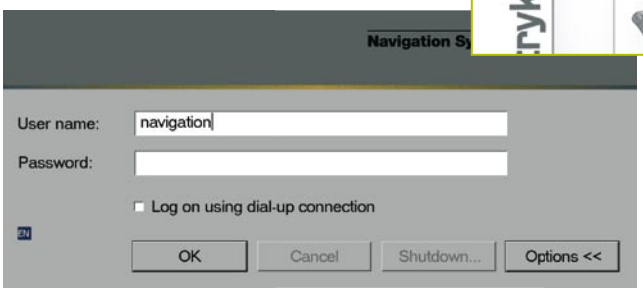
1. Set Up System and Log In ____ 4
2. Refer to Imaging Protocol ____ 5
3. Import Image Sets ____ 6
4. Confirm Patient Data ____ 11
5. Planning Features ____ 12
6. Registration Planning ____ 41
7. Set Up System ____ 45
8. Registration ____ 47
9. Pedicle Screw Navigation ____ 56
10. Insert Pedicle screw ____ 64
11. Navigated Minimal Invasive Spine Surgery with Intraoperative 3-D Imaging ____ 66
12. Calibrate Conventional Instruments ____ 88
13. Navigation Views ____ 92
14. Additional Navigation and Documentation Tools ____ 94
15. Part List ____ 98
16. Index ____ 101

1. Set Up System and Log In



1. Plug in the main power cable of the navigation system.

2. Press the main power button on the front panel of the navigation system.



3. Enter the **user name** (navigation) and press the **Enter** key or use the left mouse button to click the **OK** button.

4. After Application Manager start up, use the mouse to select **SpineMap 3-D**.

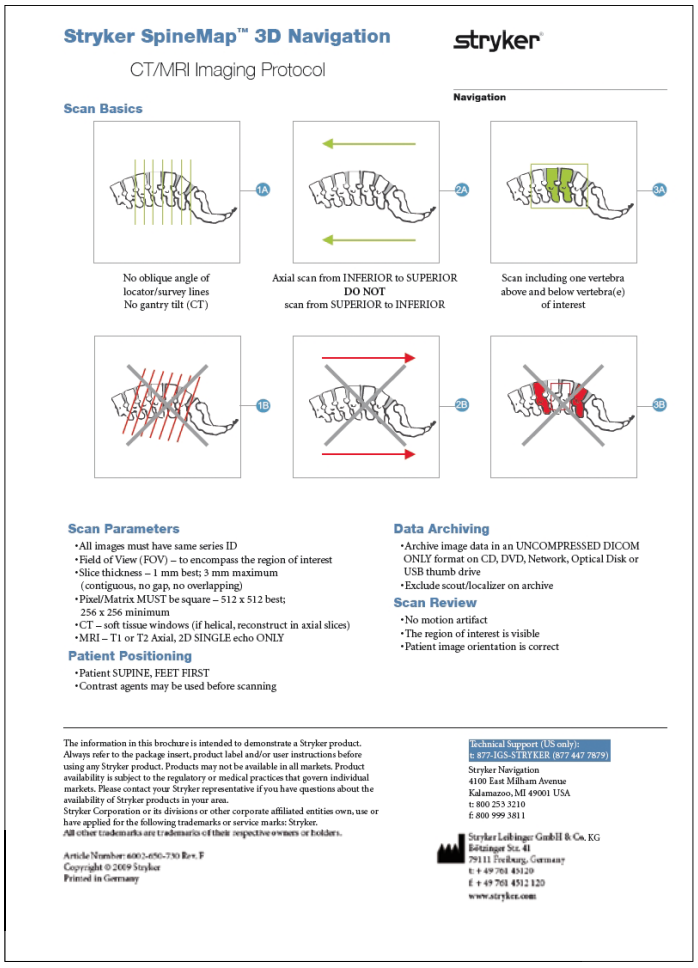
Note

The system setup can be completed by the OR support staff prior to operation.

2. Refer to Imaging Protocol

Stryker SpineMap 3-D navigation software requires a CT image set as a basis for navigation. If required, additional image sets of different modalities can be fused with the CT base images.

- For navigation efficiency and accuracy, follow the recommendations for image acquisition as depicted in the Stryker SpineMap 3-D Imaging Protocol.



Stryker SpineMap™ 3D Navigation

stryker

CT/MRI Imaging Protocol

Navigation

Scan Basics

1A — No oblique angle of locator/survey lines
No gantry tilt (CT)

2A — Axial scan from INFERIOR to SUPERIOR
DO NOT
scan from SUPERIOR to INFERIOR

3A — Scan including one vertebra above and below vertebra(e) of interest

1B

2B

3B

Scan Parameters

- All images must have same series ID
- Field of View (FOV) – to encompass the region of interest
- Slice thickness – 1 mm best; 3 mm maximum (contiguous, no gap, no overlapping)
- Pixel/Matrix MUST be square – 512 x 512 best; 256 x 256 minimum
- CT – soft tissue windows (if helical, reconstruct in axial slices)
- MRI – T1 or T2 Axial, 2D SINGLE echo ONLY

Patient Positioning

- Patient SUPINE, FEET FIRST
- Contrast agents may be used before scanning

Data Archiving

- Archive image data in an UNCOMPRESSED DICOM ONLY format on CD, DVD, Network, Optical Disk or USB thumb drive
- Exclude scout/localizer on archive

Scan Review

- No motion artifact
- The region of interest is visible
- Patient image orientation is correct

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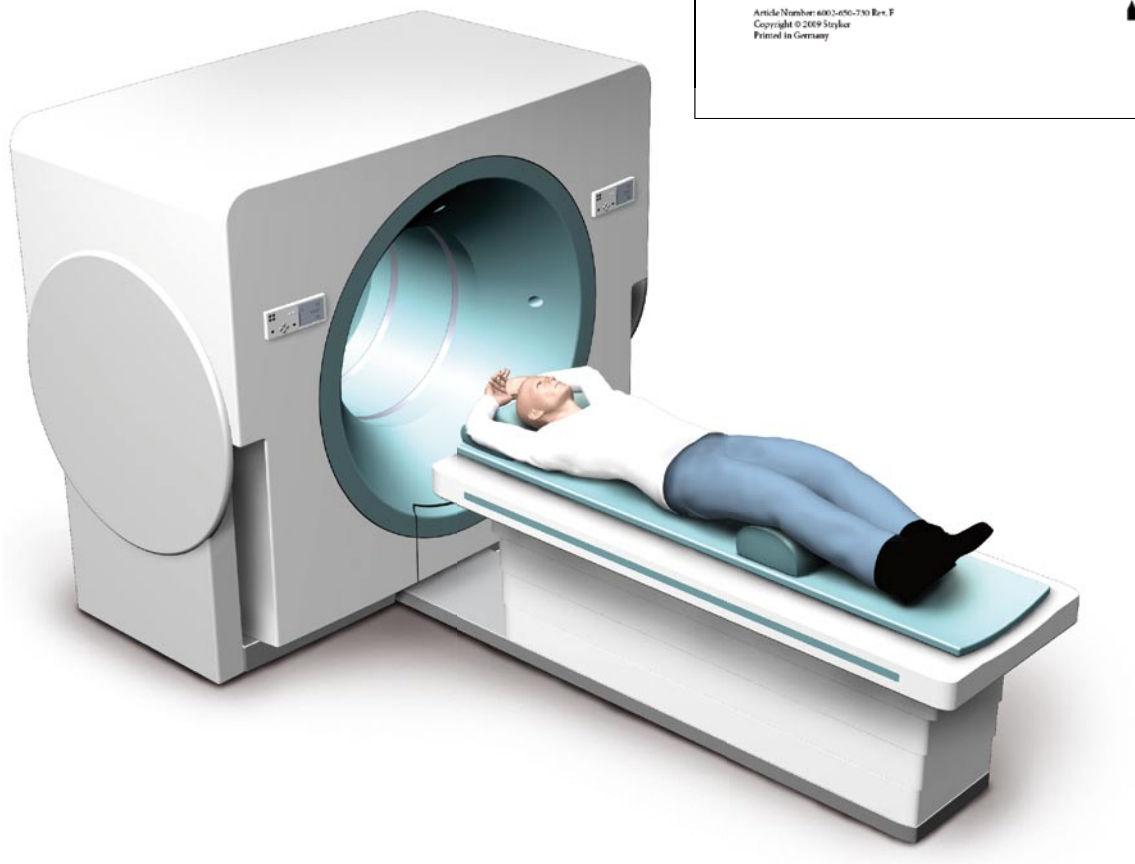
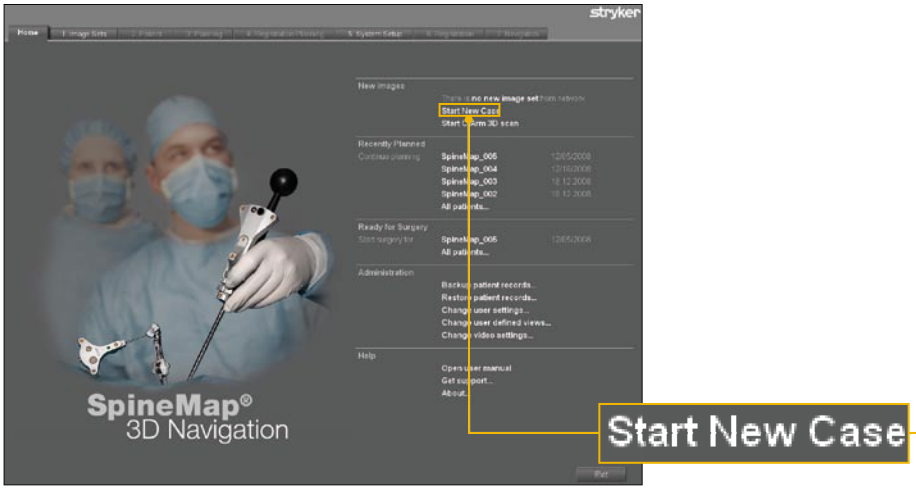
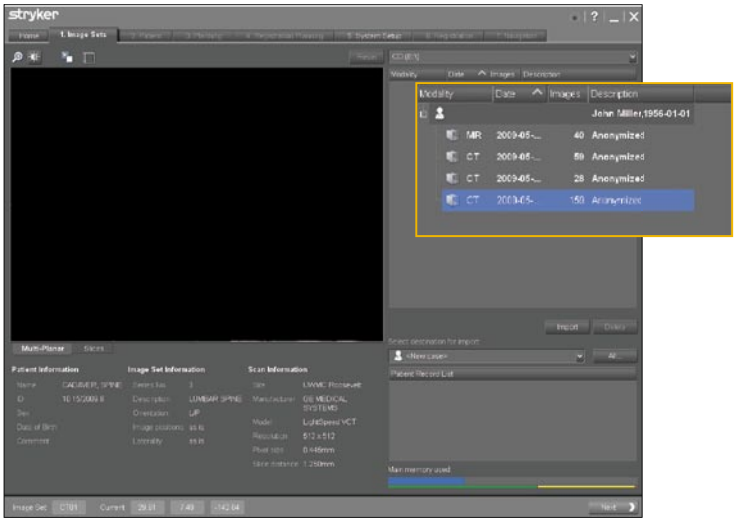
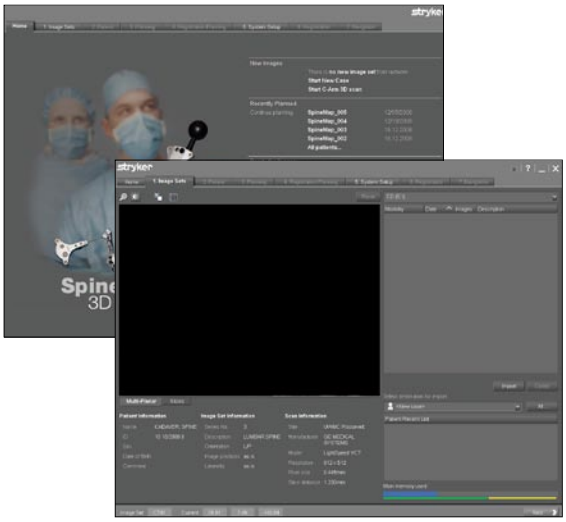


3. Import Image Sets







Step 1: Select media

Image data can be read from CD, DVD, Sony/ Maxoptix MO Disk, USB memory stick or network.

Read image data from media

- Insert the media into the appropriate drive of the navigation system.

The software detects the media and new image sets automatically. To start a new case using new image sets:

- Select the **Start New Case** link from the Home page.

The Image Sets dialog is activated by the software and the new image series are automatically listed.

Read image data from network

The software automatically detects the image files available on the network. To retrieve new image sets from the network:

- Select the **There are <n> new image sets ...** link from the Home page.

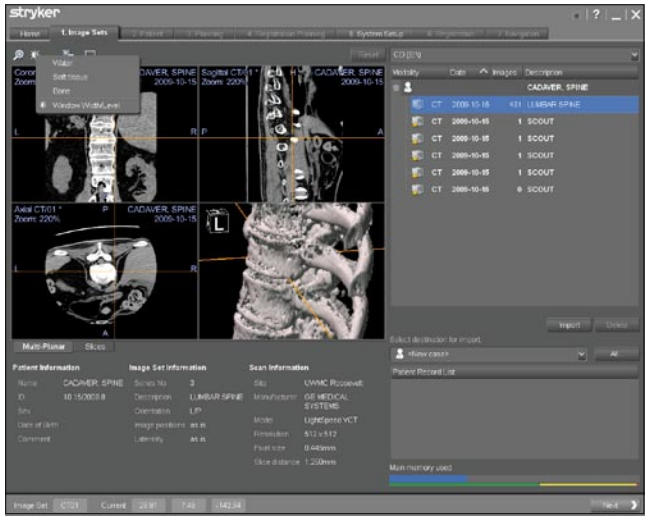
The **Image Sets** dialog is activated by the software and the new image series from the network are automatically listed.

To preview images:

- Select the required image set from the desired patient listed in the media content tree.

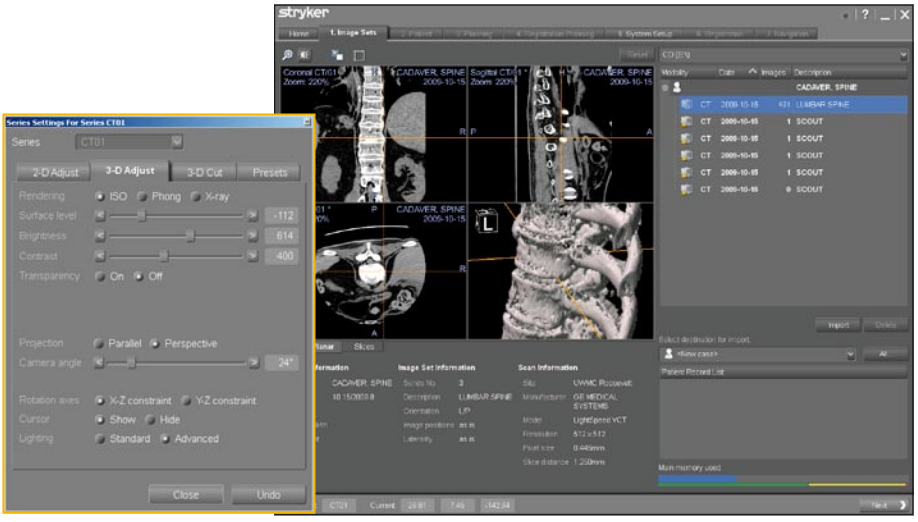
Step 2: Verify image set

Image set verification enables you to adjust the contrast and the surface level of the image set, to confirm the image orientation and to select the preferred viewing direction of images.



Adjust contrast and surface level

1. Click the icon and open the Window Width / Level box.
2. Click the **Automatic Adjust** button or use the sliders to adjust contrast (window level/ width) of the images and surface level of the 3-D rendering.



Confirm image orientation

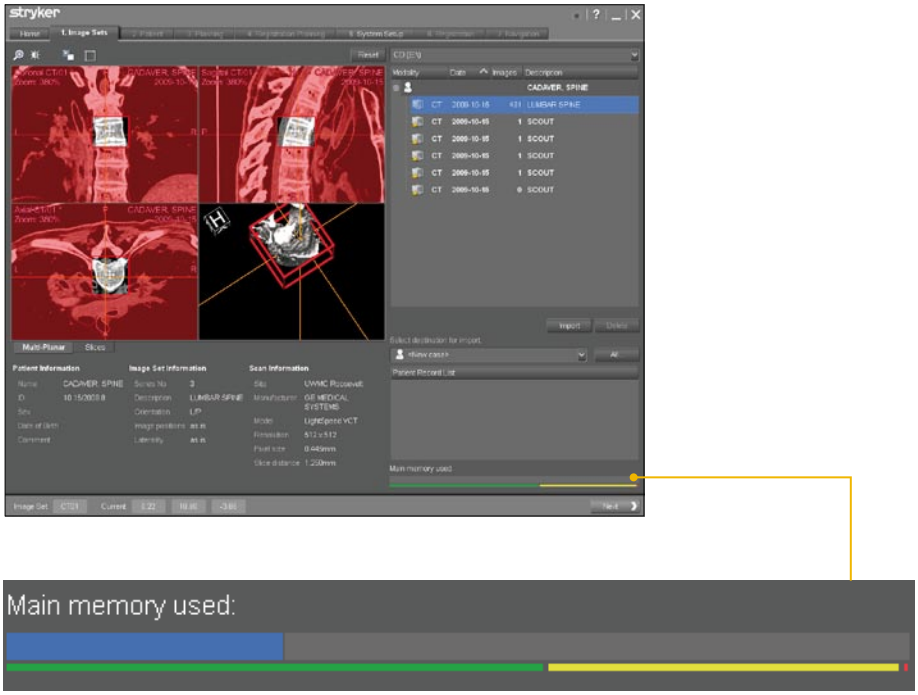
- Verify that the Image orientation labels are correct on each of the planes.

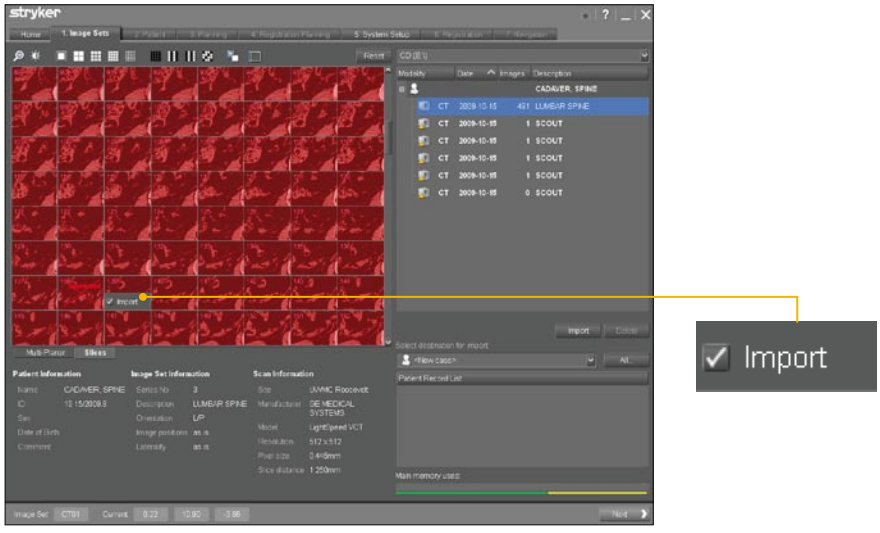
⚠ Warning

Ensure proper image orientation. Severe accuracy errors result from incorrect orientation.

If the image orientation label is incorrect:

1. Move the mouse over the orientation label requiring correction.
2. Select the correct orientation from the pull-down menu.





Step 3: Reduce image set size (optional)

If necessary, the file size of the image set to be imported can be reduced. The RAM indicator shows the used main memory of the image set to be imported.

The following procedures help you to reduce the image set file size.

Set local import bounding box

The software provides the selection of an import area of the image set.

- Use the mouse to set the bounding box over the import area.

The software imports only the part inside of the bounding box.

Select and deselect single slices

In the Slices view, single slices can be deselected.

1. Click the **Slices** tab to switch to the **Slices** view.
2. Move the mouse over the desired slice. The Import pop-up appears. Deactivate the checkbox to deselect slice.

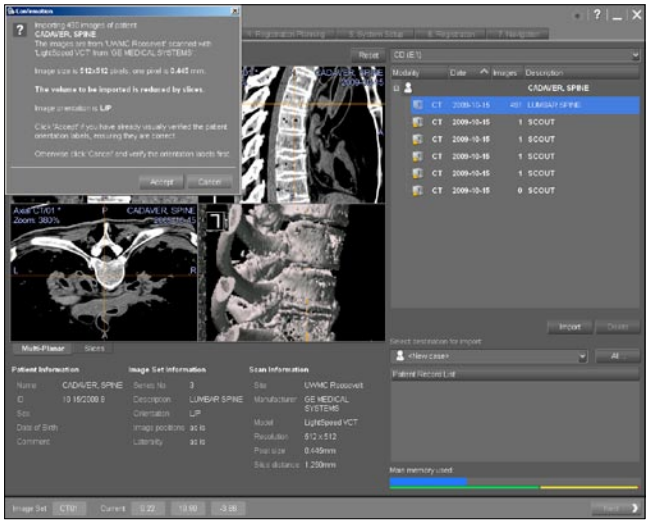
Select and deselect all/every even/every odd/every third slice

In the **Slices** view, single slices can be deselected.

1. Click the **Slices** tab to switch to the **Slices** view.
2. Click to select all/every even/every odd or every third slice.

Import image set with half resolution

The half resolution feature enables image sets to be imported in half resolution.

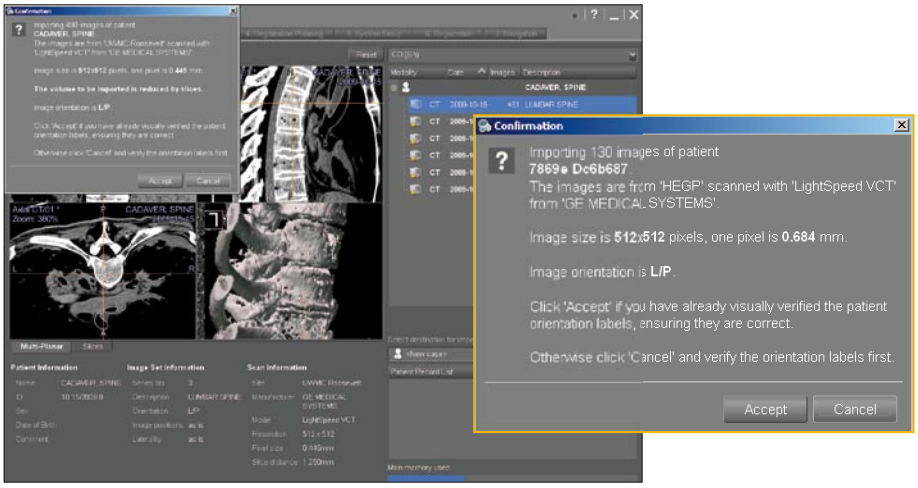


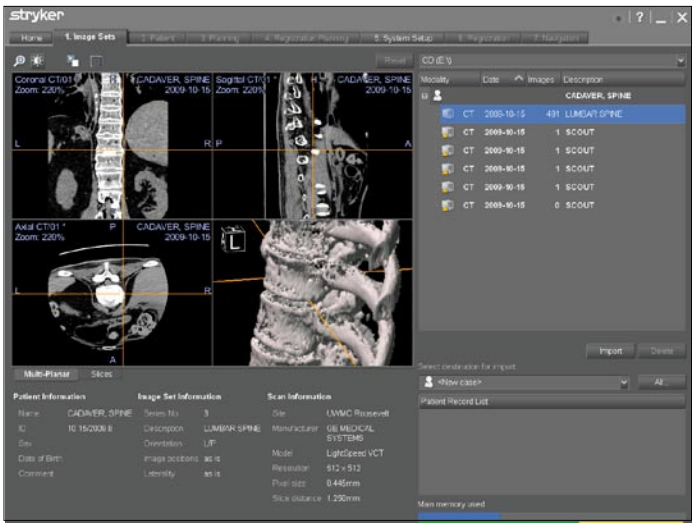
⚠ Warning

Reduction of the resolution may lead to inadequate image quality. Do not reduce the subvolume or resolution in regions in which medical indications require the available image quality. Only reduce the subvolume or resolution according to established medical standards.

It is the surgeon's responsibility to set the subvolume and resolution. In case of an unintended reduction of the subvolume or of the resolution, import the original scan again.

- Click to convert image set to half resolution.


Confirmation
Importing 130 images of patient
7869e Dc6b687
The images are from 'HEGP' scanned with 'LightSpeed VCT' from 'GE MEDICAL SYSTEMS'.
Image size is 512x512 pixels, one pixel is 0.684 mm.
Image orientation is L/P.
Click 'Accept' if you have already visually verified the patient orientation labels, ensuring they are correct.
Otherwise click 'Cancel' and verify the orientation labels first.
Accept
Cancel



Step 4: Import images

To import the selected image set:

1. Select the **Import** button.
2. Accept the confirmation message:

- ▶ Proceed to Planning.
- ▶ Import more image sets.

If required, import additional image sets for this particular patient.

- ▶ Select the desired additional image set from the media content tree.
- ▶ Repeat steps 1 and 2.

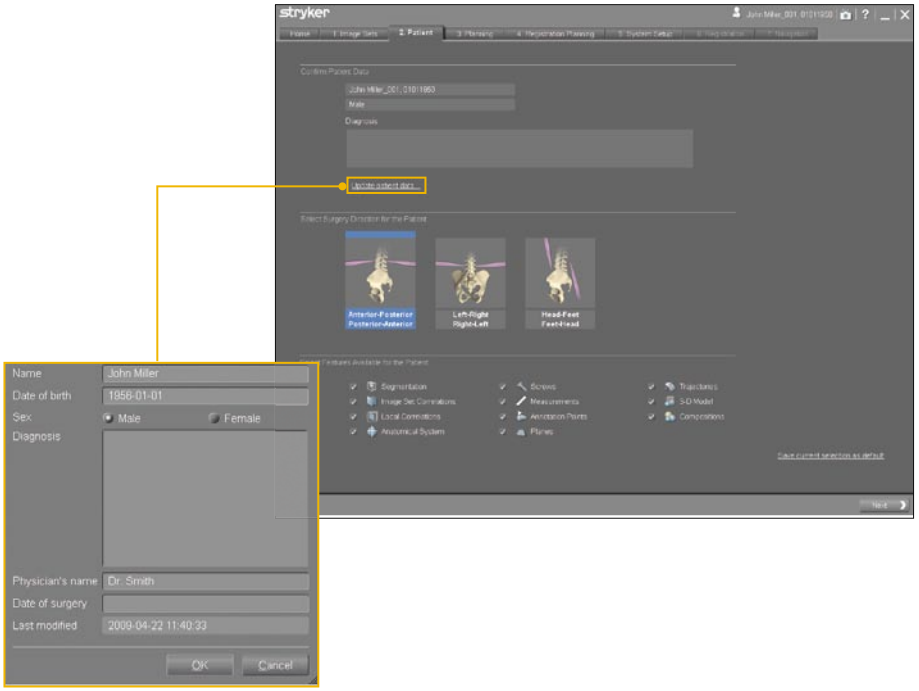
If all required image sets are imported:

- ▶ Select the **Next** button to proceed.

4. Confirm Patient Data

Step 1: Confirm patient data

- Confirm patient data listed at top of the screen.



If patient data needs to be changed or added:

1. Select the **Update Patient Data** link. The **Update Patient Related Data** window is opened.
2. Change or add patient data.

Note

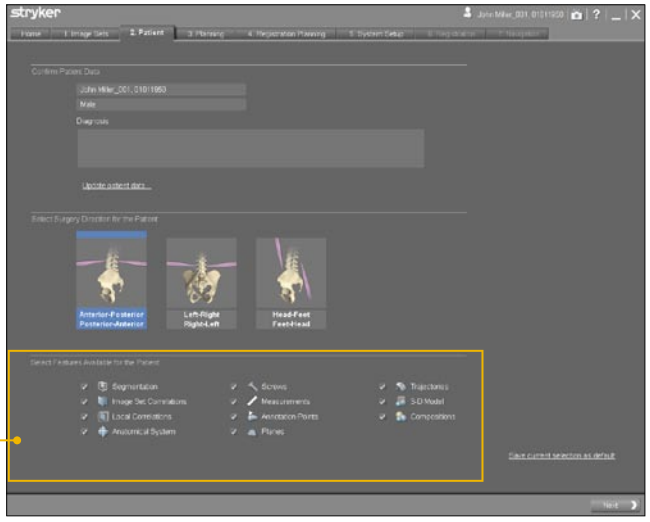
Date of birth is mandatory in order to ensure unique patient identification. If required, add the correct date of birth.

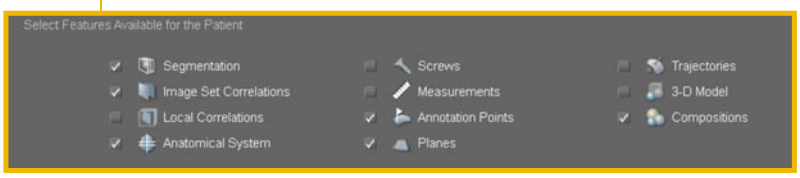
Step 2: Select surgery direction

1. Select the surgery direction required for the current patient.

Step 3: Select planning features

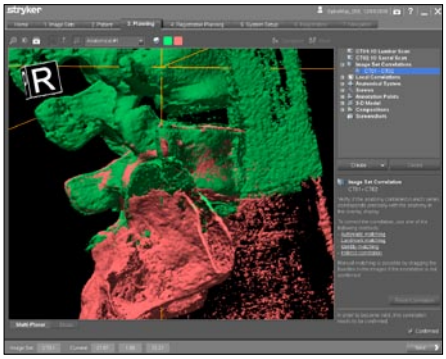
1. Select the planning features required for the current patient.
2. Select the **Next** button to proceed.



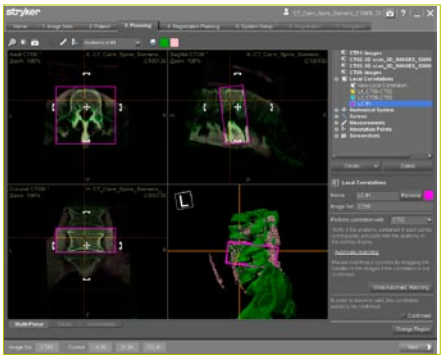


5. Planning Features

Image Set Correlations

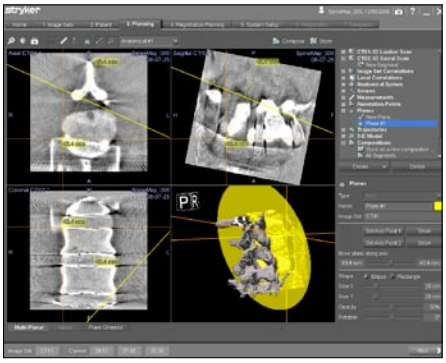


Local Correlation

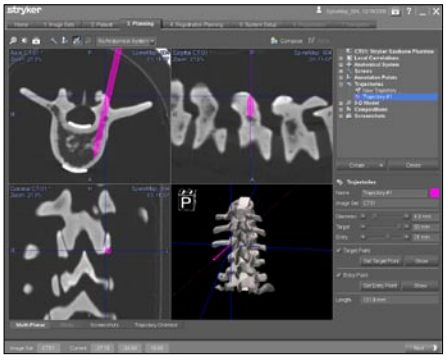


Segmentation

Planes



Trajectories



3-D Model

Overview

SpineMap 3-D software offers a vast selection of dedicated planning features. The planning features add functionality to navigation.

The features available in the Planning dialog depend on the selection made in the Patient dialog.

Image Set Correlations

Fuse multi-modal images such as CT and MRI.

Local Correlations

Select a local correlation region with an adjustable box.

Segmentation

Accentuate anatomical structures of interest such as aberrant anatomy, soft tissue, tumors, bone surfaces and vessels.

Planes

Plan and assess resection planes and the required margins.

Trajectories

Plan and assess surgical trajectories.

3-D Model

Display imported 3-D models inserted into section and 3-D images.

Anatomical System

Create multiple anatomical systems per series.

Screws

Plan and assess screws that may be required for reconstruction.

Measurements

Measure distances and angles.

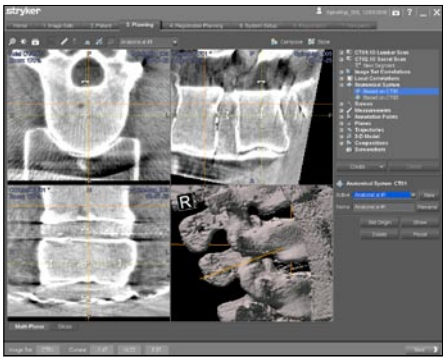
Annotation Points

Mark points of interest and add personal notes.

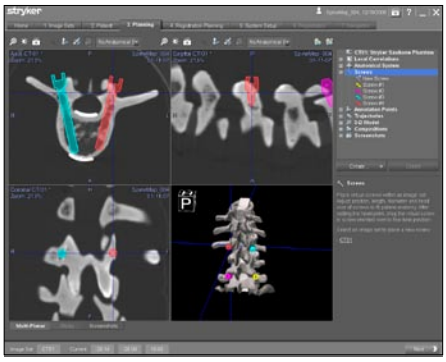
Compositions

Create image sets displaying image modalities, segments and planned items in a way best suited for the intended intervention.

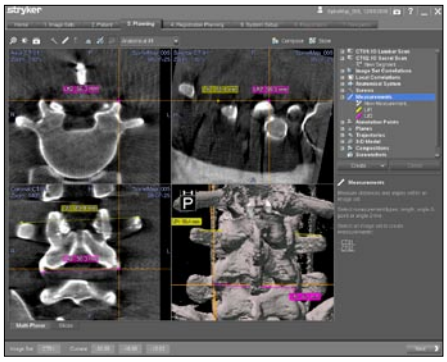
Anatomical System



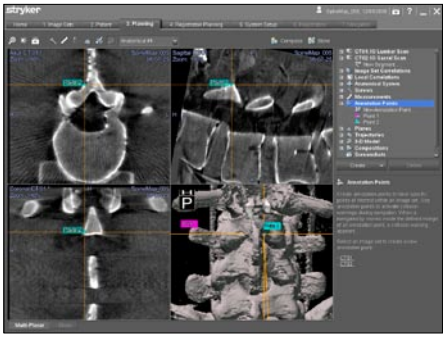
Screws



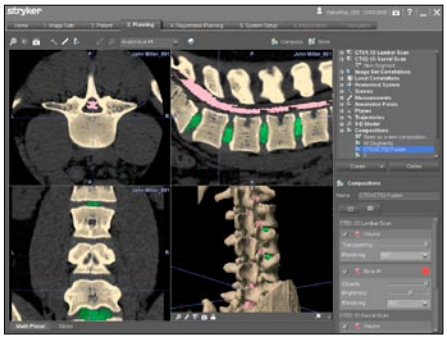
Measurements



Annotation Points



Compositions



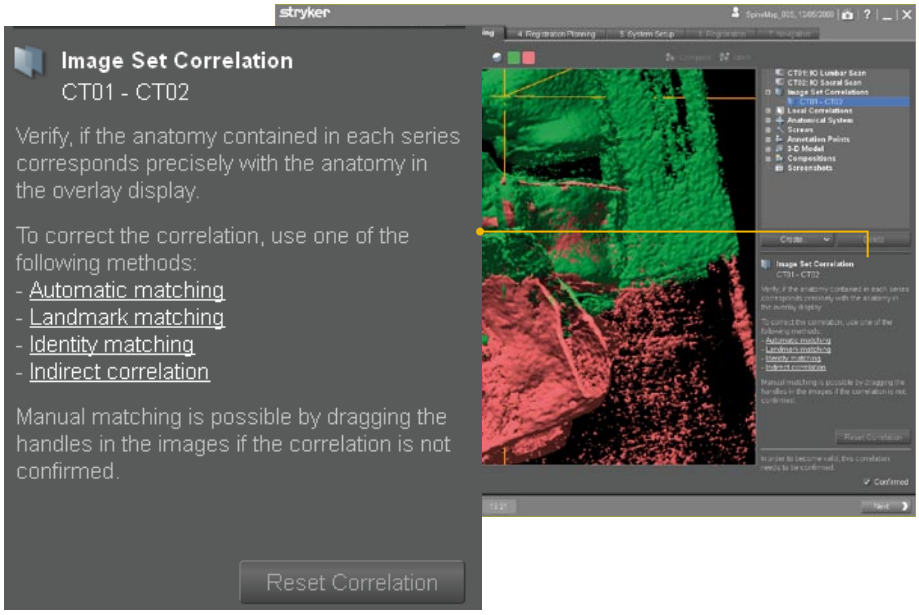


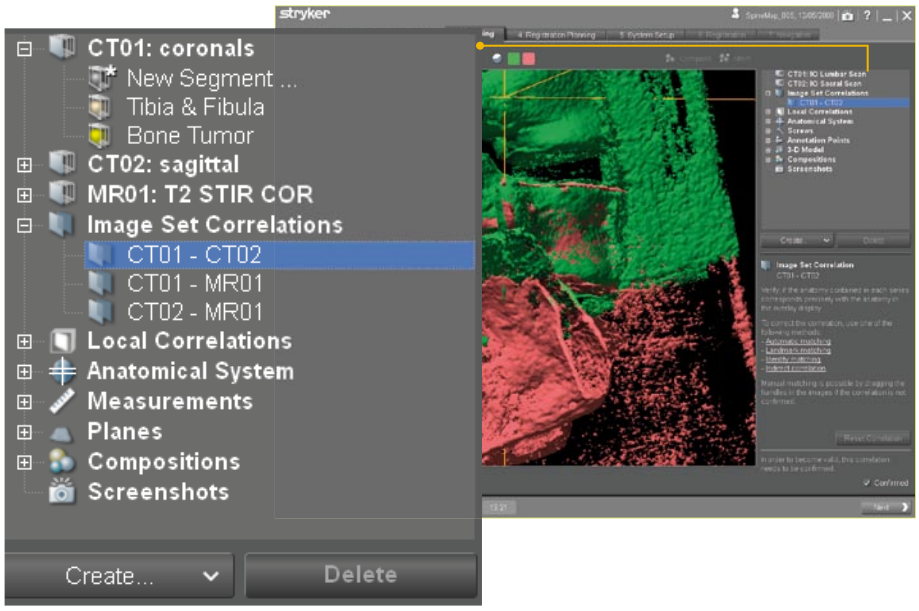
Image Set Correlation
CT01 - CT02
Verify, if the anatomy contained in each series corresponds precisely with the anatomy in the overlay display.
To correct the correlation, use one of the following methods:
- Automatic matching
- Landmark matching
- Identity matching
- Indirect correlation
Manual matching is possible by dragging the handles in the images if the correlation is not confirmed.
Reset Correlation

Image set correlations

If two or more image series for the same patient have been imported, the image correlation process can be started.

Warning

Different patient positions during imaging and movement of soft tissue may result in compromised image correlation accuracy. To achieve adequate correlation for the bony structures of interest, manual matching correction may be required.



Step 1: Select series

- Select or deselect the pairs of series to correlate.

Note

Only pairs of image sets can be correlated.

Step 2: Start automatic matching

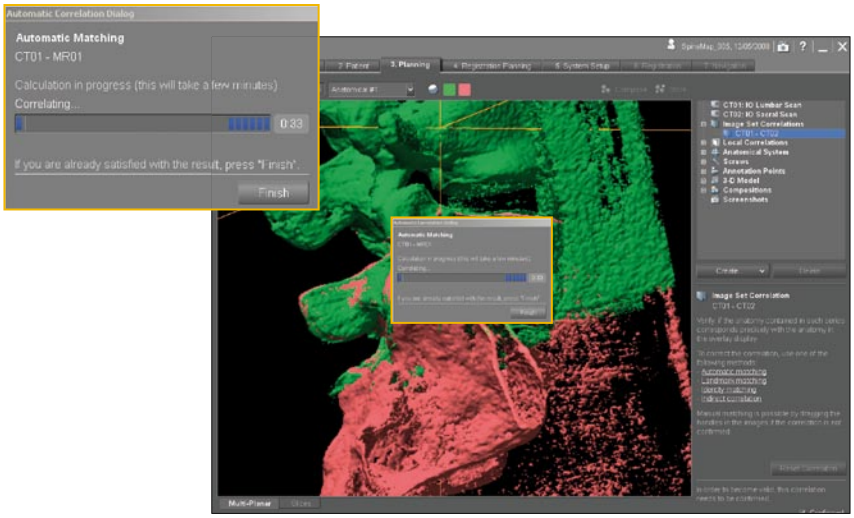
The complete automatic matching process may take a few minutes.

For better visualization of the ongoing process, the two image series are displayed in different colors.

- Click the **Automatic Matching** link to start the automatic matching process.

Note

The matching process can be terminated manually if no further alignment takes place.



Step 3: Confirm automatic matching

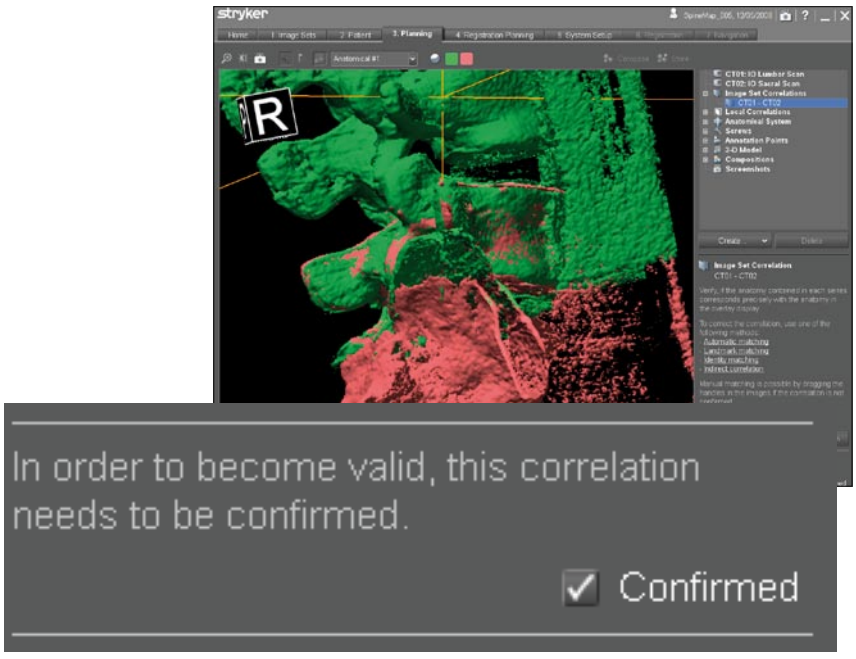
- Visually verify the suggested result of the automatic matching process by using well known landmarks.

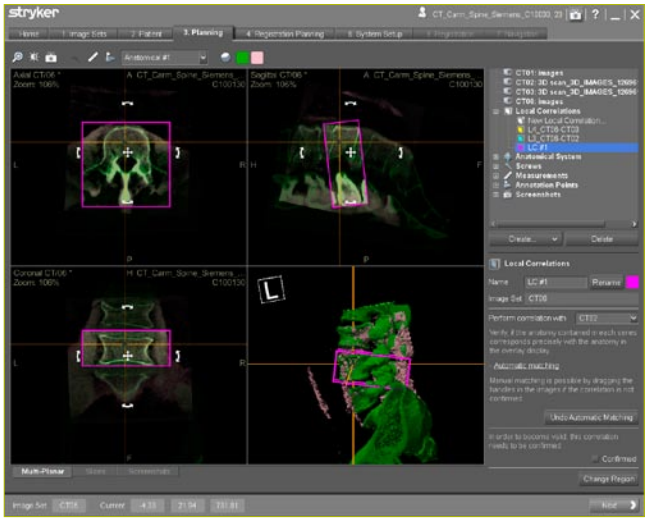
If the correlation is acceptable:

- Confirm the result by clicking the checkbox.

If automatic image correlation is not acceptable:

- Perform the **Manual matching** or activate the **Landmark matching** dialog and repeat the image correlation.





Local correlations

It is also possible to define correlation regions that are correlated to the selected navigation base series.

Warning

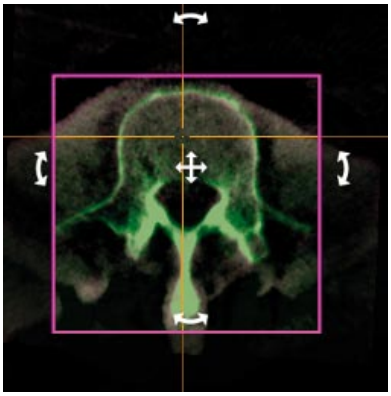
Different patient positions during imaging and movement of soft tissue may result in compromised image correlation accuracy. To achieve adequate correlation for the bony structures of interest, manual matching correction may be required by a method such as landmark matching.

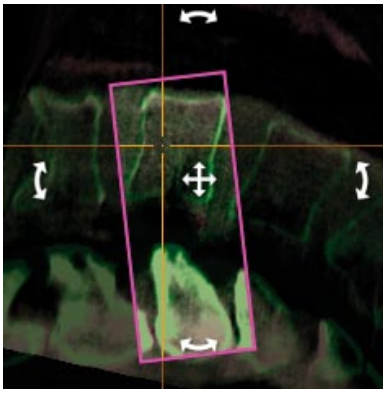
Guidelines for local correlation regions

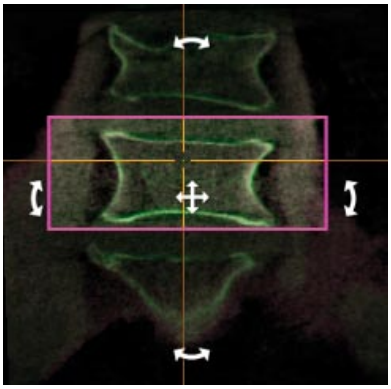
For adequate results, follow these guidelines:

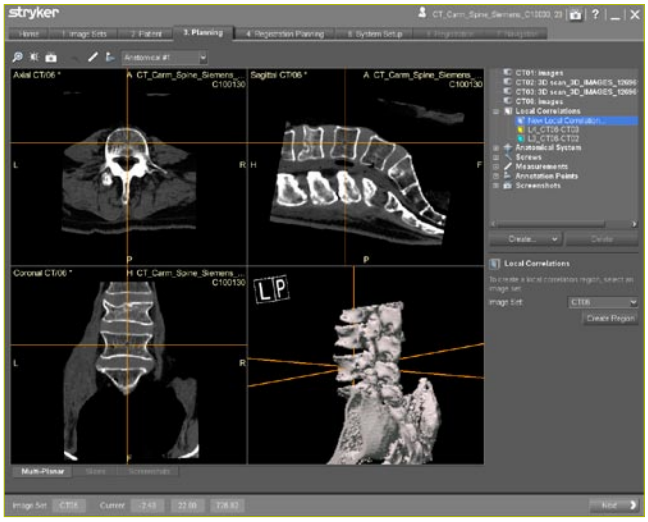
- Do not include any adjacent anatomy into the region that is connected by a joint to the target anatomy. The position of the adjacent anatomy may be different in each image set.
- Only include bony anatomy in the target region because the position of soft tissue may be different in each image set.
- The bounding box for defining the local correlation should be scaled down in all space directions so that only a vertebra or the sacrum is included.

For adequate correlation results, a local correlation for a vertebra should be defined similar to the following pictures.



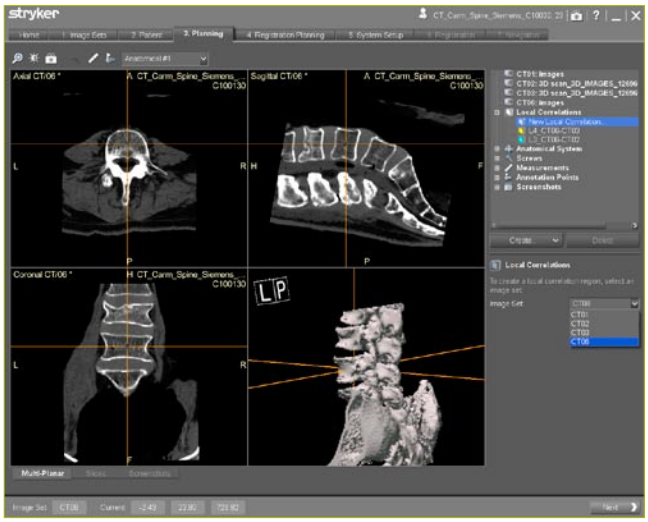




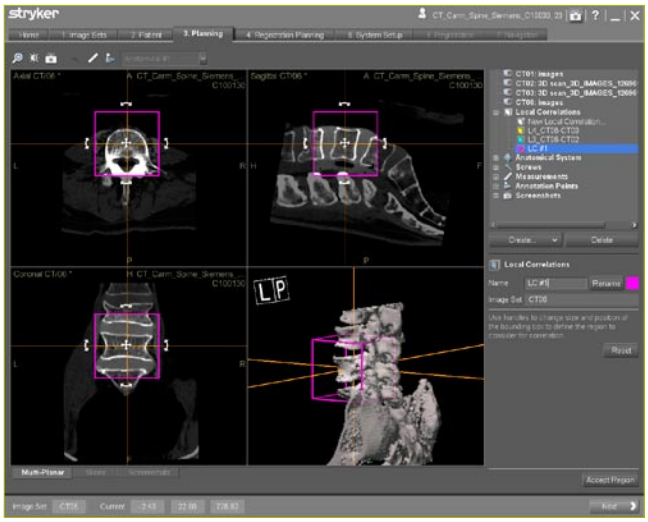


Step 1: Select series

1. Select **New Local Correlation**.
2. Position the cursor on the vertebra of interest.

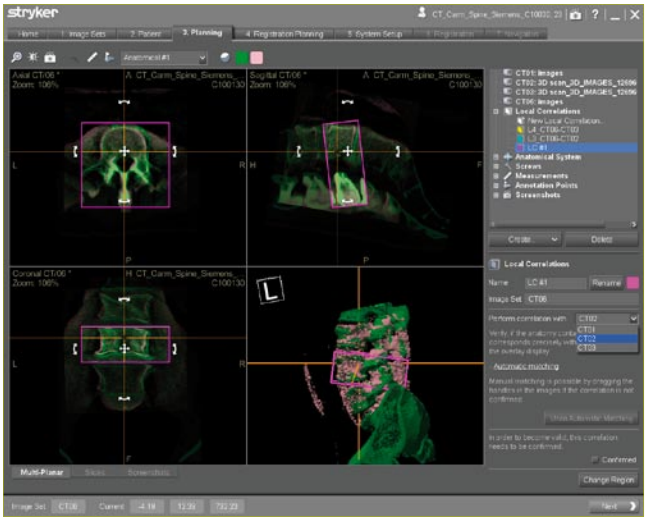


3. Select the base image series for correlation.



4. Define the correlation region with the adjustable box.

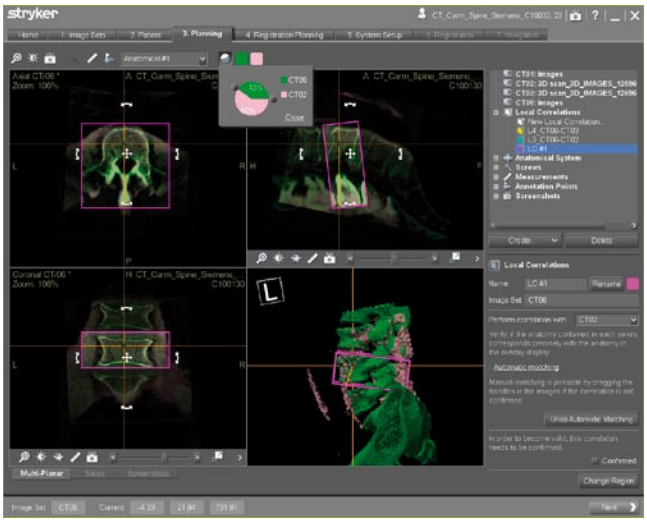
5. Select the second image series for correlation.



6. Adjust the second image series for correlation.

Note

Parts outside of the correlation region are dimly displayed. When a local correlation region is selected, the system shows the image set on which the region's adjustable box has been defined.



Step 2: Start automatic matching

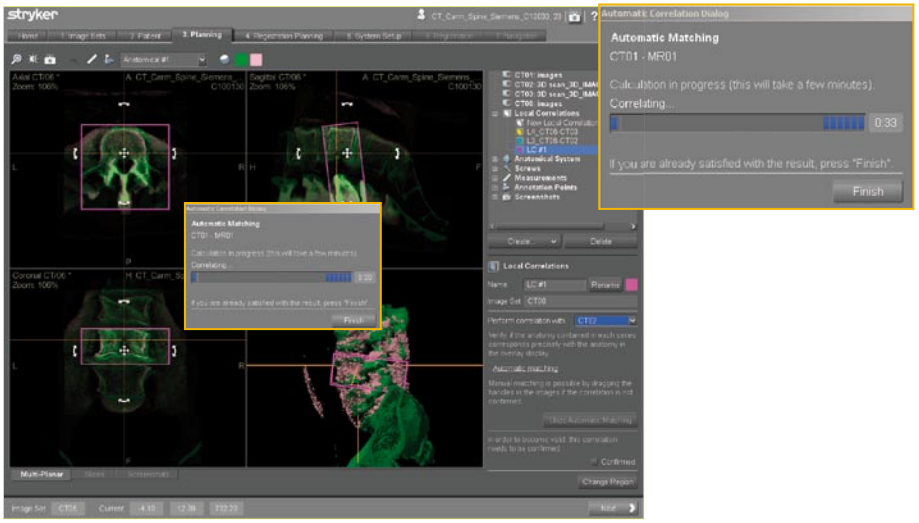
- Click the **Automatic Matching** link to start the automatic matching process.

The complete automatic matching process may take a few minutes.

For better visualization of the ongoing process, the two image series are displayed in different colors.

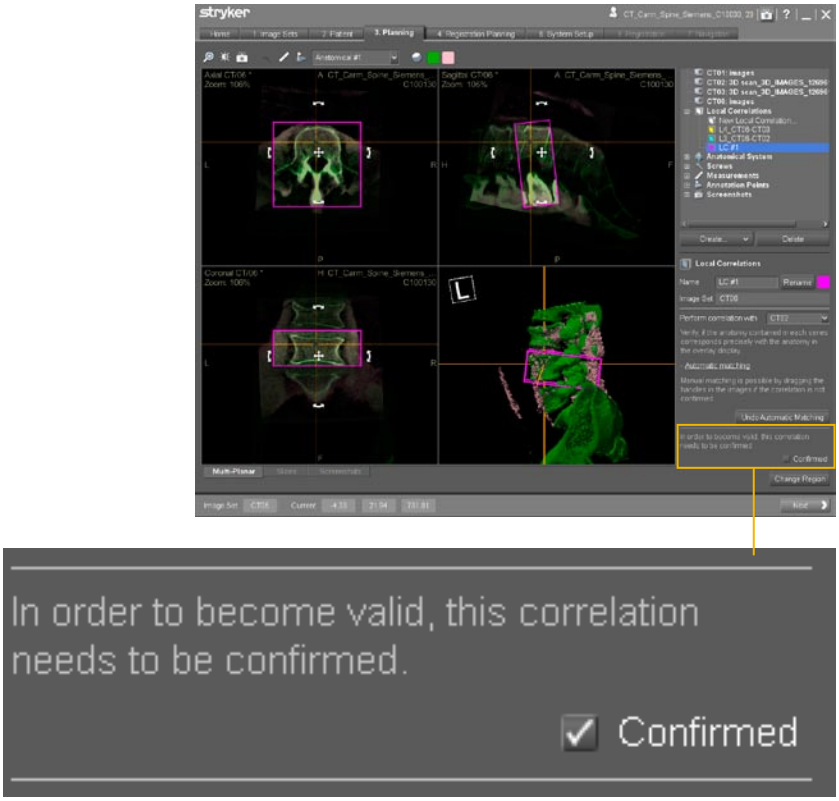
To check the result during the matching process:

- Click the ● icon and use the image box functionality.


Automatic Matching
CT01 - MR01
Calculation in progress (this will take a few minutes).
Correlating...
If you are already satisfied with the result, press "Finish".
Finish

Note

The matching process can be terminated manually if no further alignment is needed.



Step 3: Confirm automatic matching

- Visually verify the accuracy of the automatic matching process by using well known landmarks.

If the correlation is accurate:

- Confirm the result by clicking the **Confirmed** checkbox.

If automatic image correlation is not satisfactory:

- Perform the **Manual matching** or activate the **Landmark matching** dialog and repeat the image correlation.

Segmentation

There are two segmentation workflows.

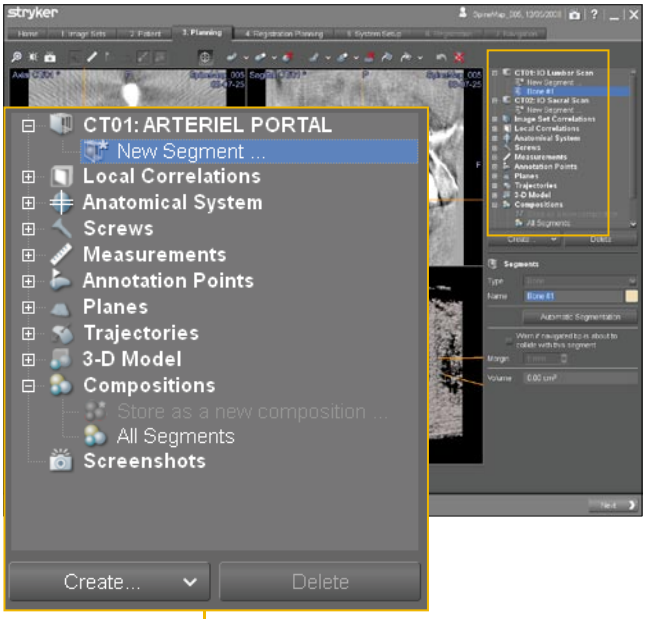
⚠ Warning

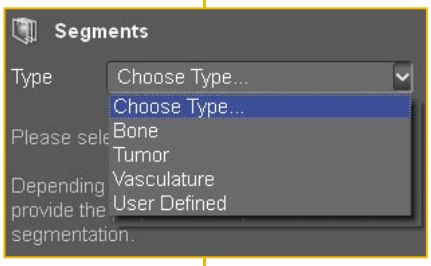
During navigation, soft tissue movement may result in erroneous navigational information of the (segmented) soft tissue anatomy. For each segment, a safety margin can be defined. During navigation, the software warns surgeons visually and audibly as soon as the navigated tool tip enters this safety margin.

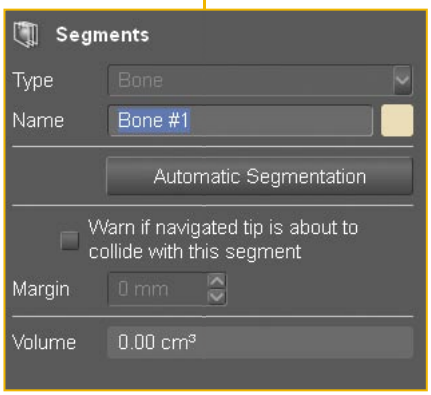
Step 1: Define segment type

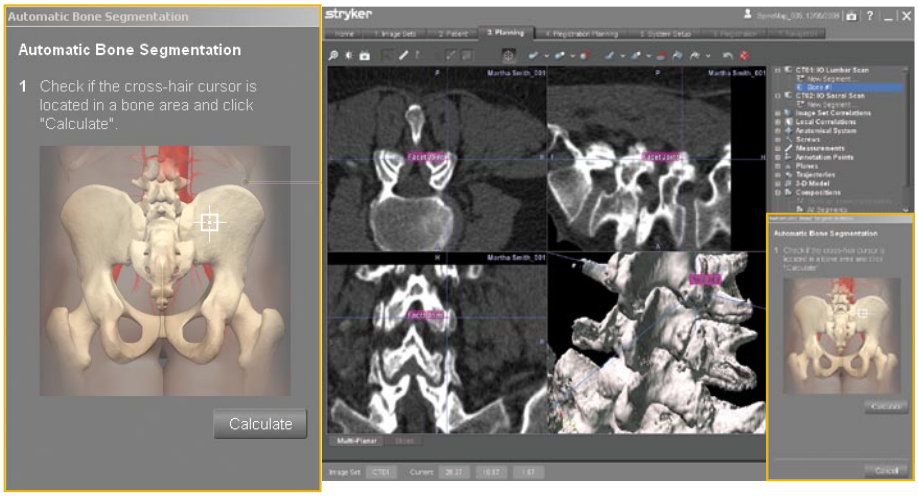
1. Double-click the image set that best shows the volume of interest (for example CT for bone segmentation and MR for tumor segmentation).
2. Select **New Segment** below the selected image set. Upon selection, the **Segmentation** tool panel is displayed.

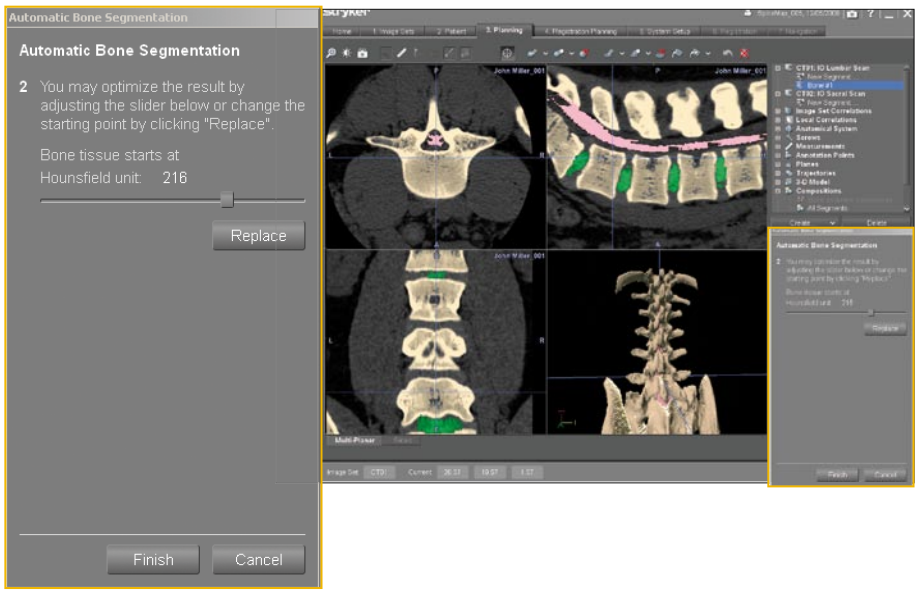
- Select one of the pre-defined segment types from the pull-down menu: **Bone, Tumor, Vasculature or User Defined**. The **Segmentation** tool panel is expanded.
- Select the **Automatic Segmentation** button.








Automatic Bone Segmentation
Automatic Bone Segmentation
1 Check if the cross-hair cursor is located in a bone area and click "Calculate".
Calculate


Automatic Bone Segmentation
Automatic Bone Segmentation
2 You may optimize the result by adjusting the slider below or change the starting point by clicking "Replace".
Bone tissue starts at
Hounsfield unit: 216
Replace
Finish
Cancel

Step 2: Start automatic segmentation

1) Bone Segmentation

1. If required, limit the segmentation space by moving the boundaries of the rectangular segmentation box displayed in the 2-D and 3-D views.
2. Set the crosshair cursor in an area displaying the bone to be segmented.
3. Select the **Calculate** button. The bone is segmented.
4. Assess the visibility and borders of the segmented bone in the 2-D and 3-D views.

If the bone is segmented insufficiently:

- Lower the Hounsfield threshold to add more cartilage or thin bone to the bony structures by moving the Hounsfield unit slider.

If the bone is satisfactorily segmented:

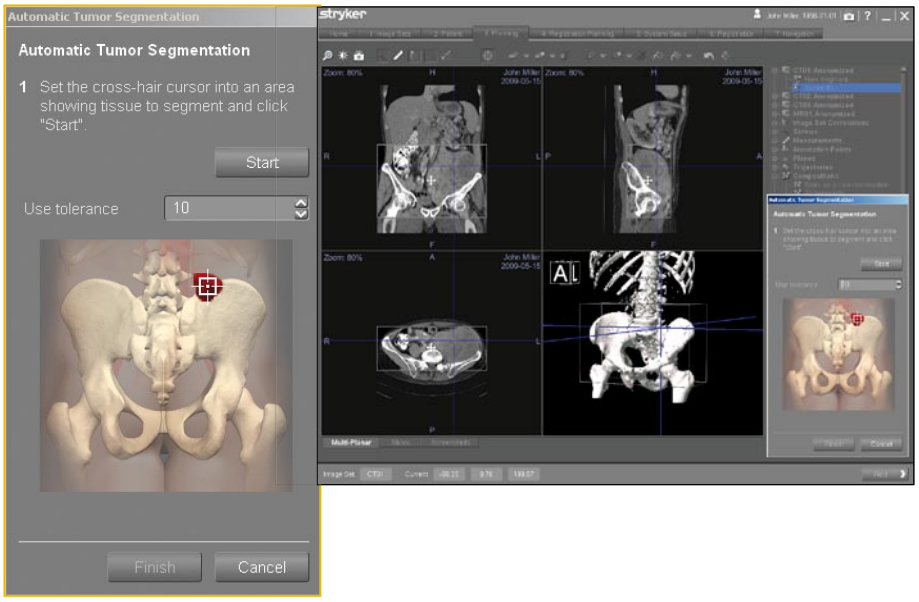
- Click the **Finish** button to finalize and save the bone segment.

Note

Automatic bone segmentation works only with CT image sets.

2) Tumor/ Vasculature/ User Defined Segmentation

1. If required, limit the segmentation space by moving the boundaries of the rectangular segmentation box displayed in the 2-D and 3-D views.
2. Set the crosshair cursor into an area showing tissue to segment.
3. Select the **Start** button. The structure of interest is segmented.
4. Assess the visibility and borders of the segmented structure in the 2-D and 3-D views.

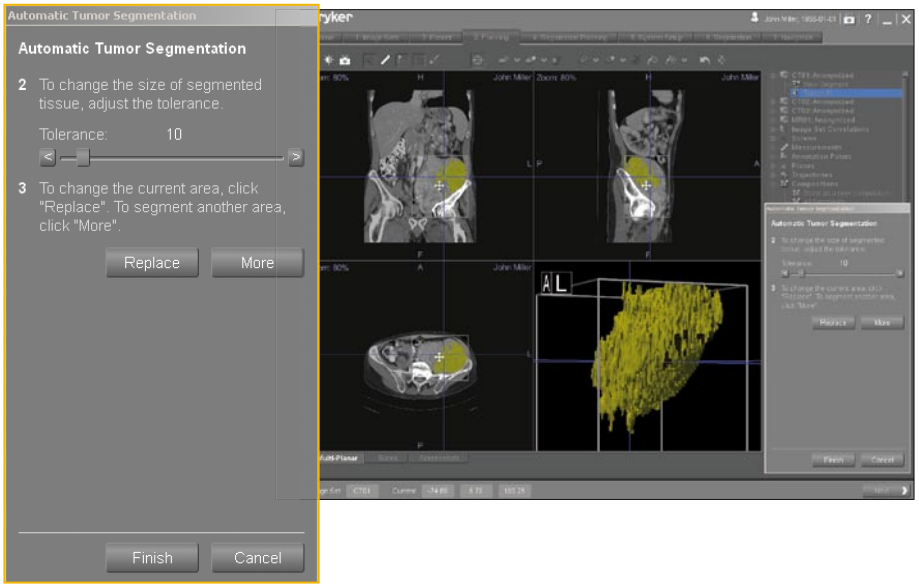


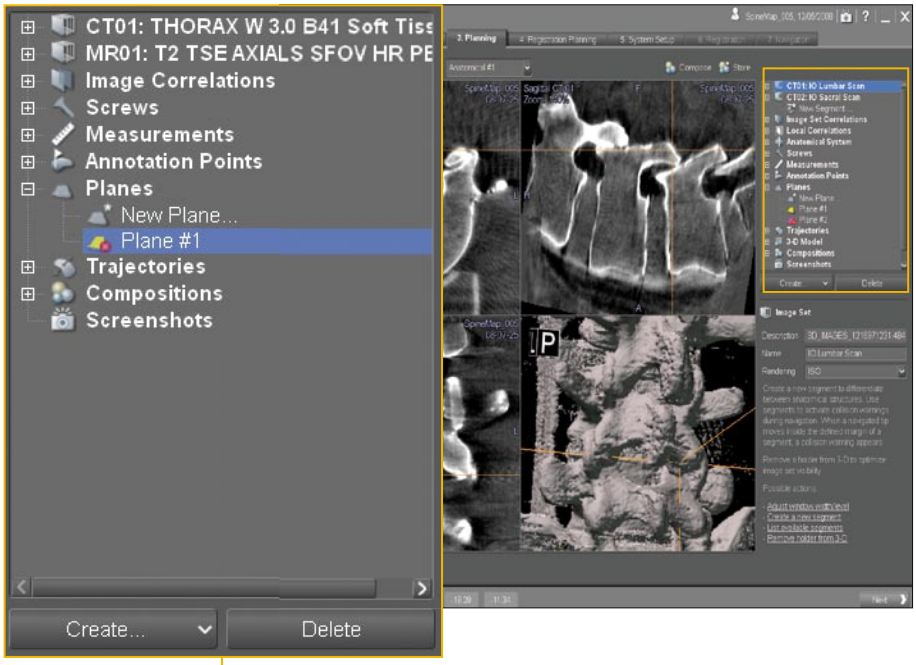
If the structure of interest is segmented with imperfect borders:

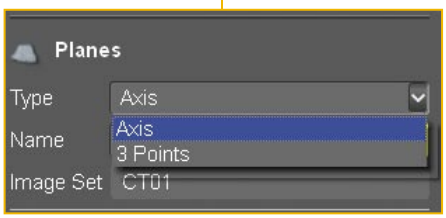
- Move the **Tolerance** slider until the structure of interest has reached its optimal visibility.

If the structure of interest is segmented partially and not sufficiently connected to be segmented in one instance:

- Add a new portion to the structure already segmented by clicking the **More** button and by repeating the **Segmentation** dialog.
- Once the structure is satisfactorily segmented, click the **Finish** button to finalize and save the segment.







Planes creation

There are two options for resection plane planning: digitizing an initial axis perpendicular to the desired resection plane or digitizing three points to define the desired plane.

Planes are commonly planned for pelvectomies, sacrectomies and long bone resections.

For long bones the axis based resection plane enables easy alignment of perpendicular cutting planes to the bone shaft.

Step 1: Create new plane

1. Select the image set in which a plane is to be defined by clicking the image set item in the patient record tree.
2. Double-click the **Planes** item and select **New Plane**. Upon selection, the **Planes** tool panel is displayed.

Step 2: Select method for plane creation

- Select the desired plane creation method from the pull-down menu: **Axis or 3 Points**. The tool panel is expanded for the selected plane functionality.

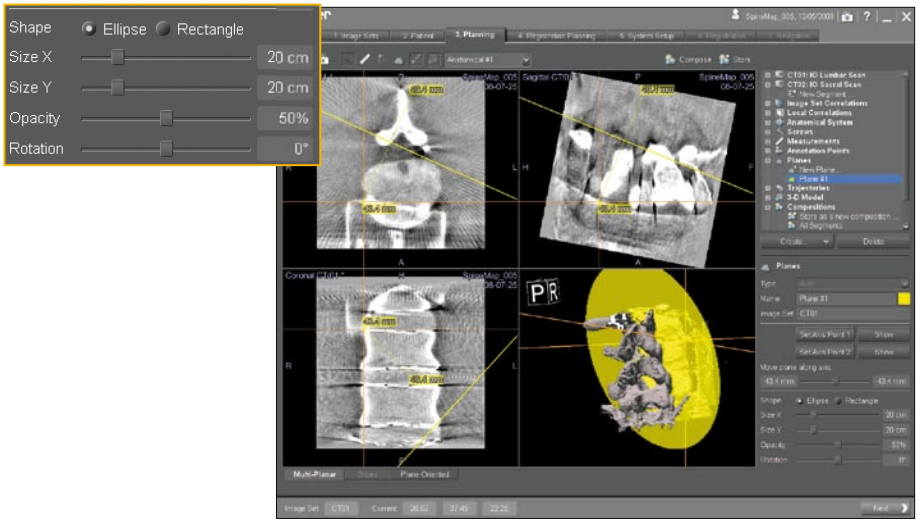
Step 3: Create new planes

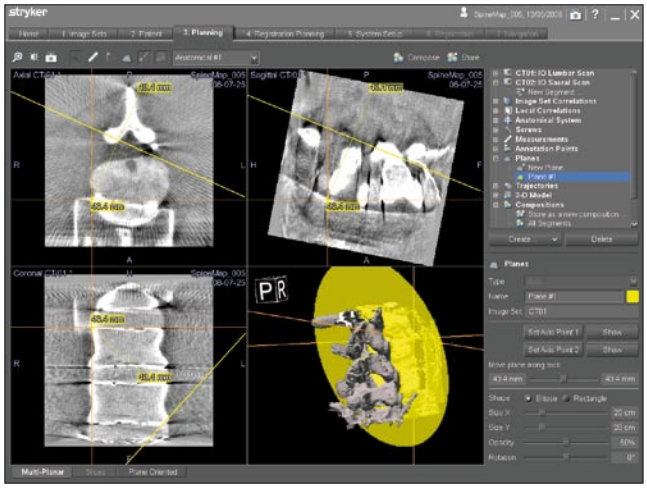
1) Axis Method

1. Set the crosshair cursor on the first point of a virtual axis that lies perpendicular to the desired plane (for example the proximal center point of a bone shaft).
2. Select the **Set Axis Point 1** button to record the position.
3. Set the crosshair cursor on the second point of the virtual axis perpendicular to the desired plane (for example the distal center point of a bone shaft).
4. Select the **Set Axis Point 2** button to record the position. A plane perpendicular to the digitized axis is displayed.
5. Select the **Plane Oriented** tab.
6. Make sure that the plane and bony intersection mark the resection line appropriately.

If required:

- Adjust the shape (Ellipse/ Rectangle), the size (Size X, Size Y), the opacity, and the rotation of the plane using the radio buttons and the sliders.





To assess plane position and orientation:

- Grab and move the handles of the red dotted line and assess the margins of the planned resection plane.

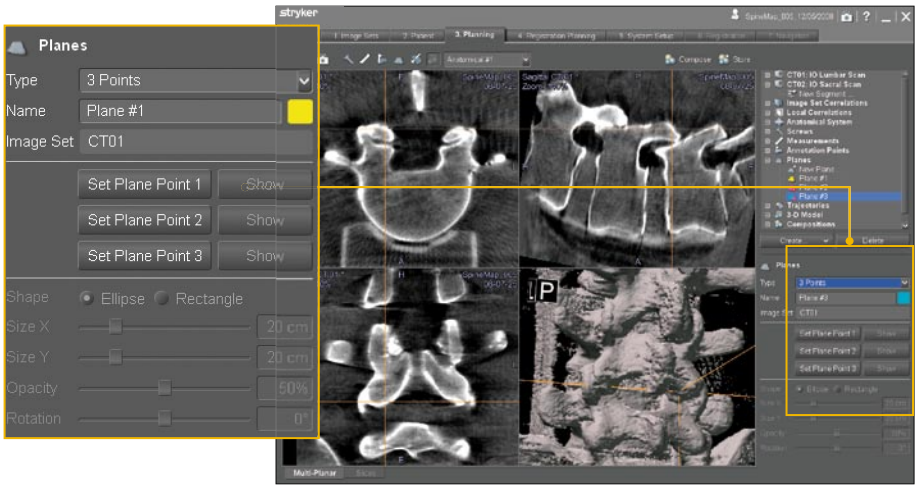
If required:

- Move the plane along the digitized axis to the desired position using the **Move** plane along the axis slider or by grabbing the plane.
- Change the orientation of the plane by grabbing and moving the axis points.

Note

Click the icon to hide or display all planes.

To navigate planes, a composition including the plane has to be created and recalled for navigation.



2) 3 Point Method

1. Set the crosshair cursor on the first point of the intended plane.
2. Select the **Set Plane Point 1** button to record the position.
3. Define and record the second and third points of the intended plane. A plane defined by the three digitized points is displayed.
4. Select the **Plane Oriented** tab.
5. Make sure that the plane and bony intersection mark the resection line appropriately.

If required:

- Adjust the shape (Ellipse/ Rectangle), the size (Size X, Size Y), the opacity and the rotation of the plane using the radio buttons and the sliders.

To assess plane position and orientation:

- Ensure that the crosshair cursor does lie on the plane by clicking any **Show** button of the tool panel.
- Grab and move the handles of the red dotted line and assess the margins of the planned resection plane. Move the plane along the digitized axis to the desired position using the **Move** plane along the axis slider or by grabbing the plane.

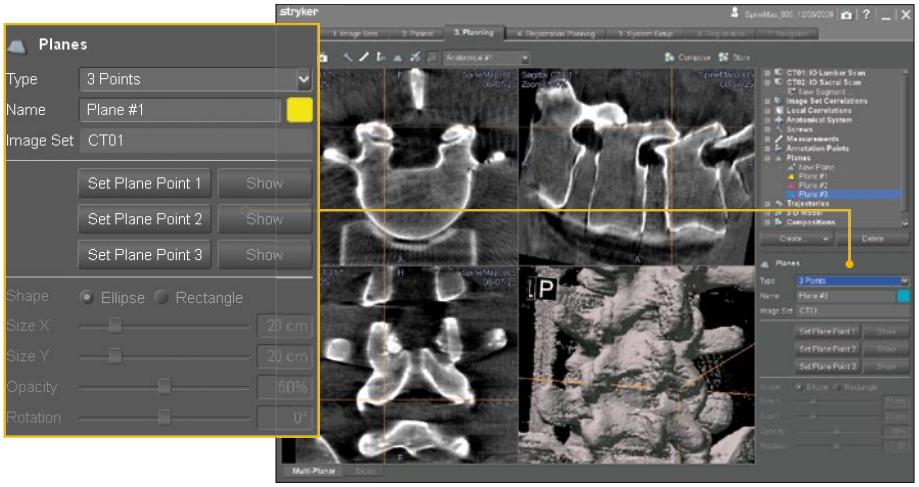
If required:

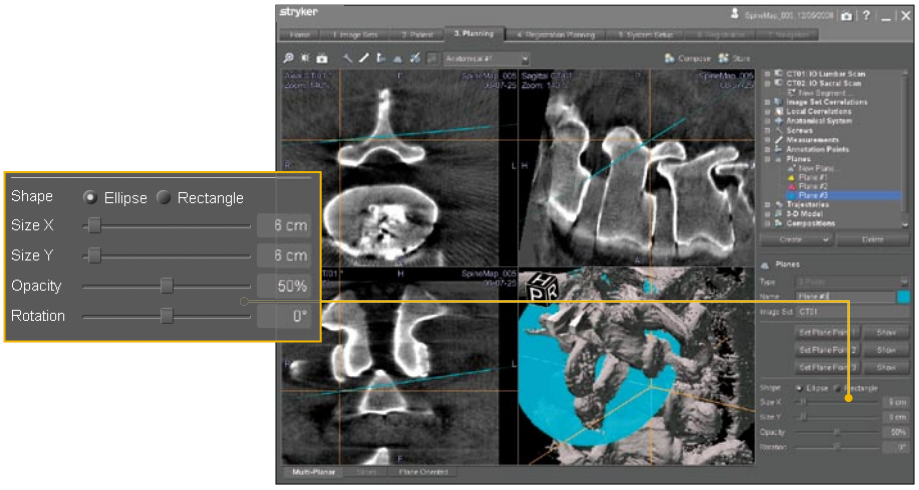
- Change position and orientation of the plane by grabbing and moving the plane points.

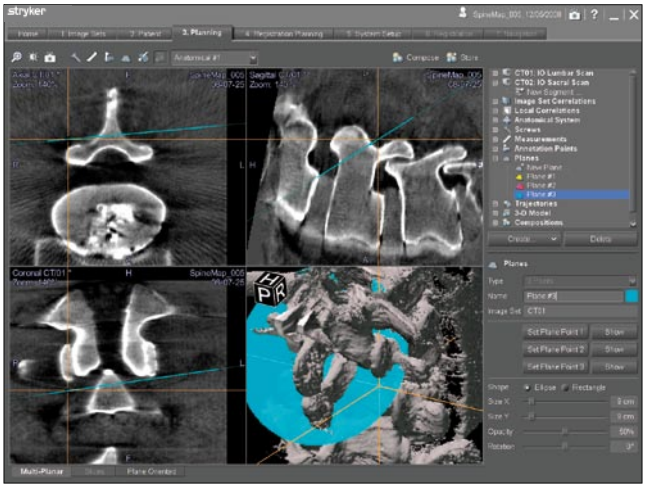
Note

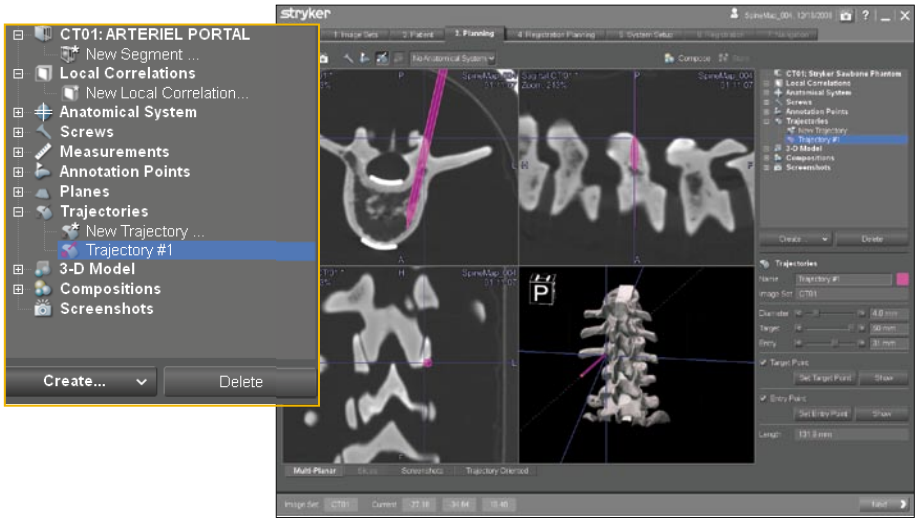
Click the icon to hide or display all planes.

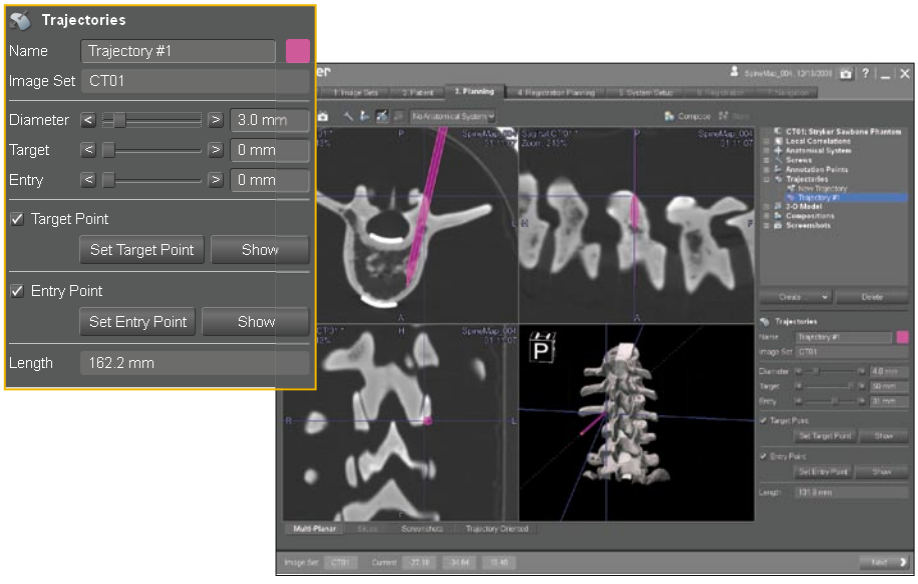
To navigate planes, a composition including the plane has to be created and recalled for navigation.











Trajectories creation

A trajectory connects a target and an entry point. Trajectories can also be used to measure total limb length and to define an axis for implant alignment.

Step 1: Create trajectory

1. Select the image set in which a trajectory is to be defined by clicking the image set item in the patient record tree.
2. Double-click **Trajectories** and select **New Trajectory**. Upon selection, the **Trajectories** tool panel is displayed.

Step 2: Define target point

1. Set the crosshair cursor on the target point of the desired trajectory.
2. Select the **Set Target Point** button to record the position.

Step 3: Define entry point

1. Set the crosshair cursor on the entry point of the trajectory.
2. Select the **Set Entry Point** button to record the position.

If required:

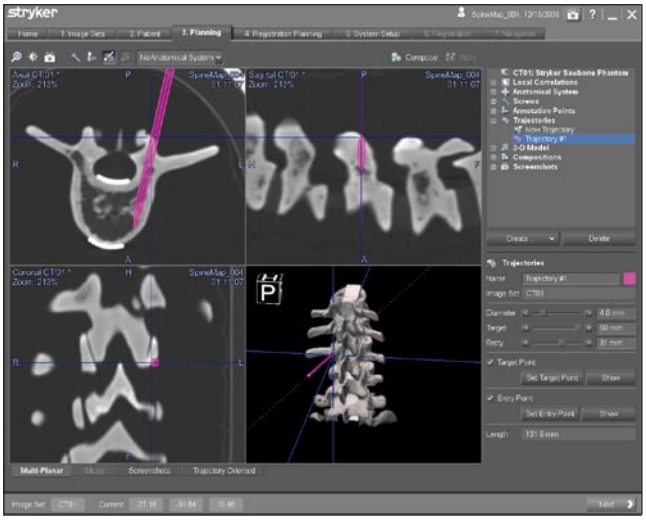
- Change the parameters of the Trajectory by adjusting the Diameter, Target and/or Entry slider.

Step 4: Assess trajectories

1. Select the **Trajectory Oriented** tab.
2. Grab and move the handles of the red line in the **Along 90** or **Along 0** window and assess the trajectory slice by slice through a perpendicular cut.

If required:

- Change the planned trajectory by grabbing and moving the entry or target point.



Note

Click the icon to hide or display all trajectories.

In the 3-D image, the displayed trajectory is extended beyond the digitized entry point to provide guidance if the entry point is subcutaneous. The position of the digitized entry point is marked with a staged ring on the 3-D approach.

3-D model display

The 3-D model can be used in existing correlations and compositions.

Colors of the 3-D models can be changed for optimum visualization.

Note

Each imported 3-D model belongs to only one corresponding series. When a series is deleted, the corresponding 3-D models are deleted too.

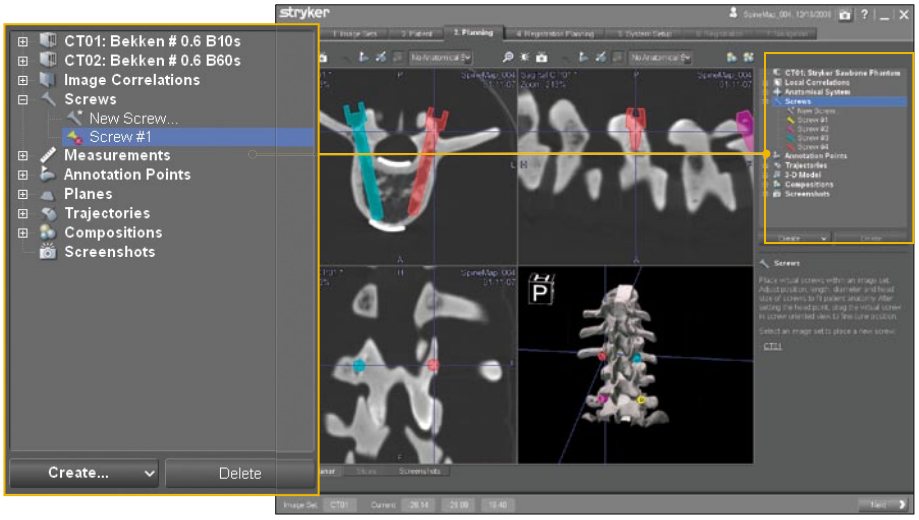
Step 1: Import model

1. Double-click **3-D Model** and select **Import 3-D Model** in the patient record tree.
2. Select the image set in which a 3-D model should be imported in the drop down menu.
3. Click **Import Model** and choose the 3-D model that should be imported.
4. Move crosshair cursor to the desired position and click **Set Rotation-Center** to set the rotation center of the 3-D model.
5. Check the size and geometry of the 3-D model. If necessary, position the 3-D model to the desired position.
6. Click the **Confirmed** checkbox to confirm 3-D model.

Screw creation

Step 1: Activate tool panel

1. Select the image set in which a screw is to be defined by clicking the image set item in the patient record tree.
2. Double click **Screws** and select **New Screw**. Upon selection, the **Screws** tool panel is displayed.

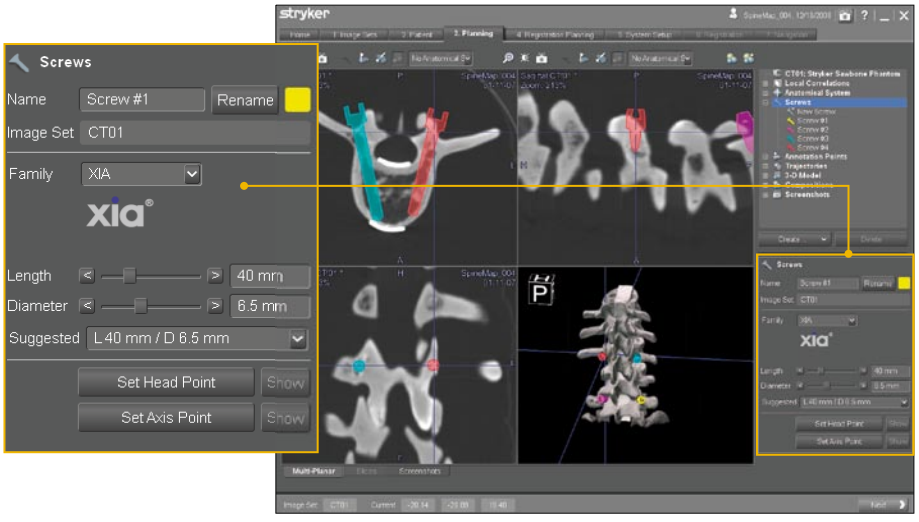


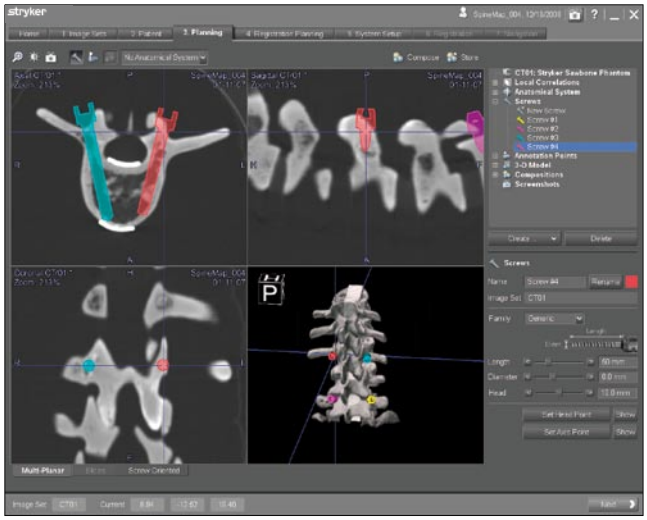
Step 2: Define head and axis point

1. Set the crosshair cursor on the desired screw head position.
2. Select the **Set Head Point** button to record. The view changes automatically to **Screw Oriented**.
3. Set the crosshair cursor on the desired screw axis position.
4. Select the **Set Axis Point** button to record.

Note

Click the icon to hide or display all screws.





Step 3: Adjust screw

- Grab and move the handles of the red line in Along 90 or Along 0 window and assess the screw position and orientation slice by slice through a perpendicular cut.

If required:

- Redefine the screw position and orientation by first selecting the **Screw Oriented** tab, then grabbing and moving the screw tip, the screw head or the entire screw.
- Adjust the screw size, the screw length and the screw head size using the sliders of the tool panel.

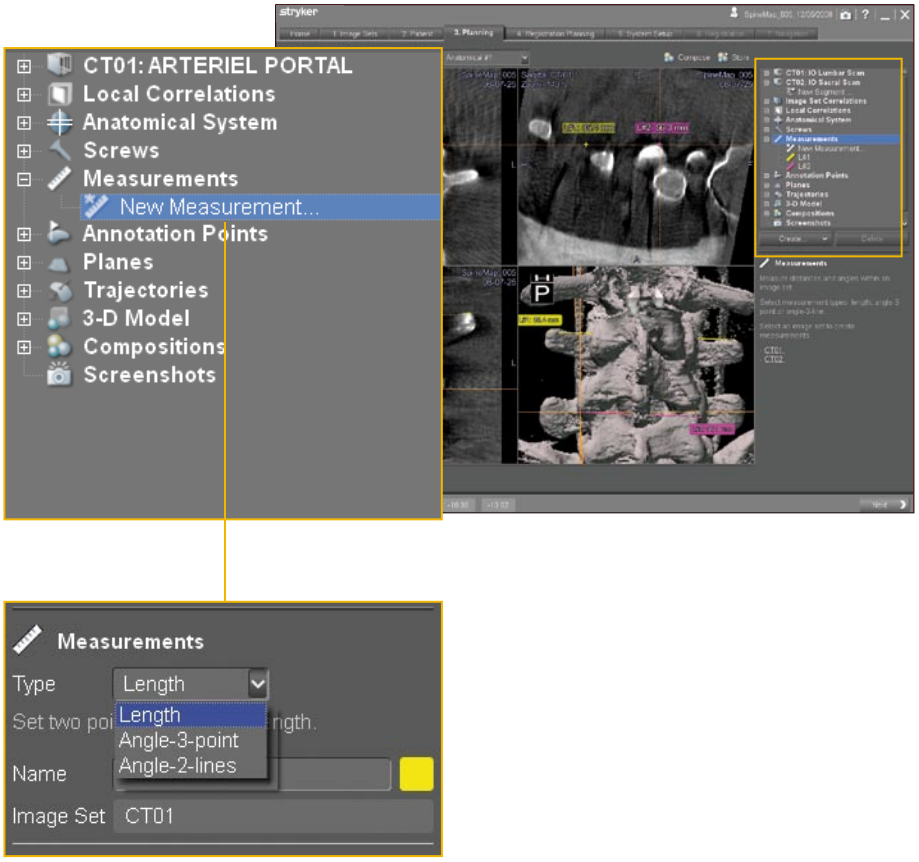
Note

Click the icon to hide or display all screws.

Measurement creation

There are three measurement tools. One to measure lengths, one to measure the angle between two lines and one to measure the angle created by three points.

Measurements can also be performed intraoperatively during navigation by using the tracked instrument tip. Measurements performed during navigation are added and stored similar to preoperative measurements.

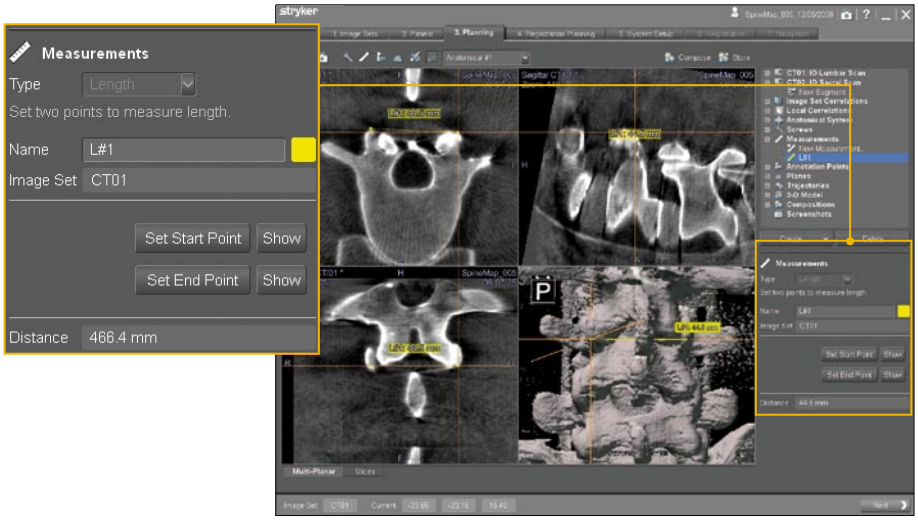


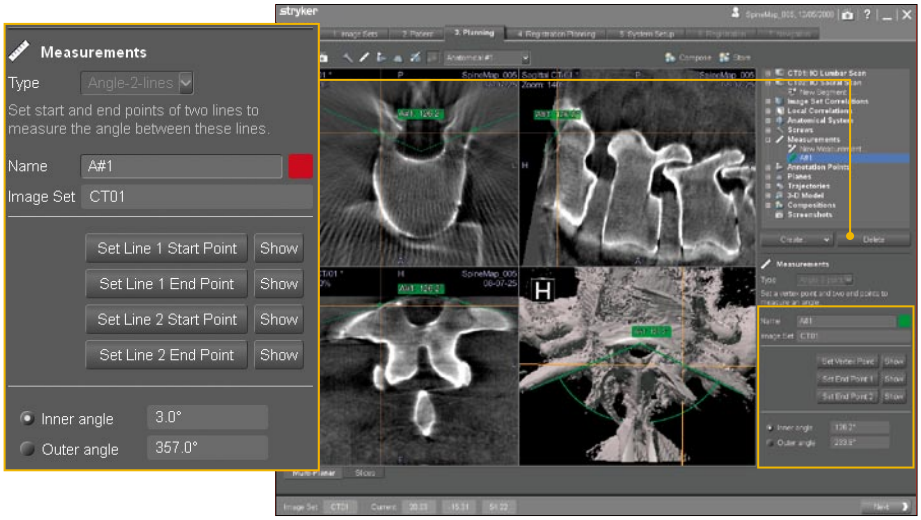
Step 1: Activate tool panel

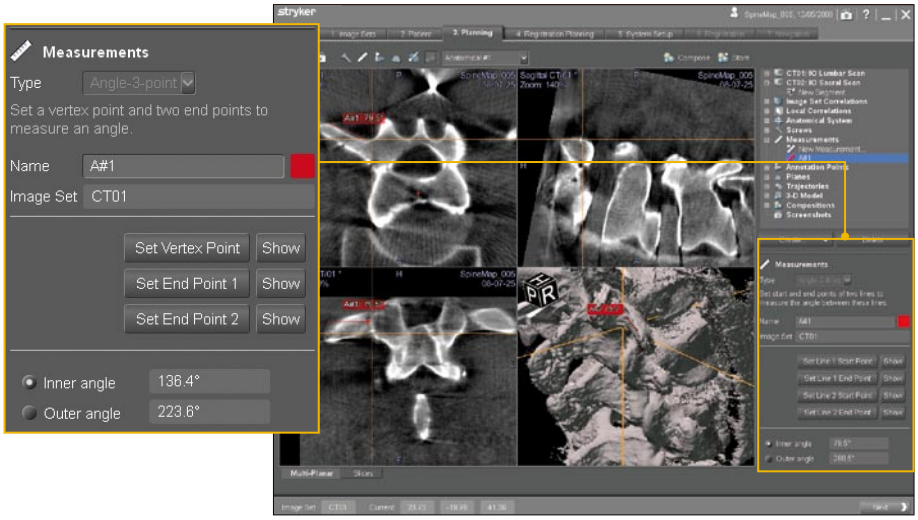
1. Select the image set in which a measurement is to be done by clicking the image set item in the patient record tree.
2. Double-click **Measurements** and select **New Measurement**. Upon selection, the **Measurements** tool panel is displayed.

Step 2: Select measurement

- Select the desired measurement from the pull-down menu: **Length, Angle-3-point or Angle-2-lines**. The tool panel is expanded for the selected measurement functionality.







Step 3: Create measurement types

1) Length Measurement

1. Set the crosshair cursor on the start point of the line.
2. Click the **Set Start Point** button to record.
3. Define and record the end point of the line.

If required:

- Redefine the length measurement by grabbing and moving the start and end point of the line.

2) Angle - 2 Lines Measurement

- Define and record the start and end points of two lines.

For angle calculation, the two lines are projected in one plane.

If required:

- Redefine the Angle - 2 lines measurement by grabbing and moving the start and end point of the two lines.

3) Angle - 3 Point Measurement

- Define and record the vertex, the start and the end point of the angle.

If required:

- Redefine the Angle - 3 point measurement by grabbing and moving the start, the vertex and the end point of the angle.

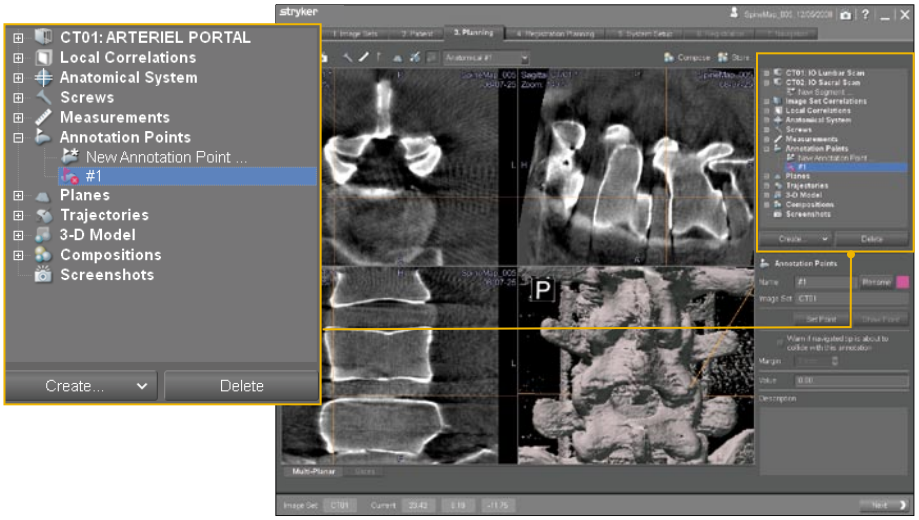
Note

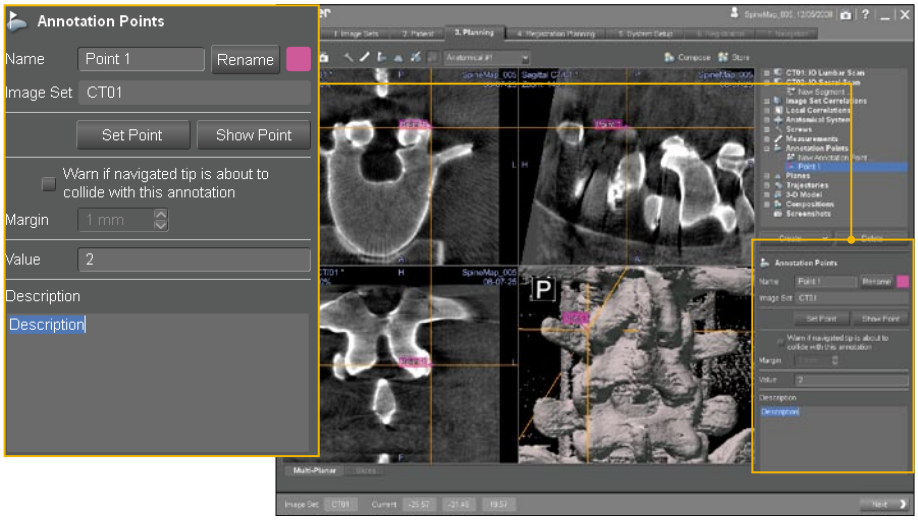
Use the icon to hide or display all measurements.

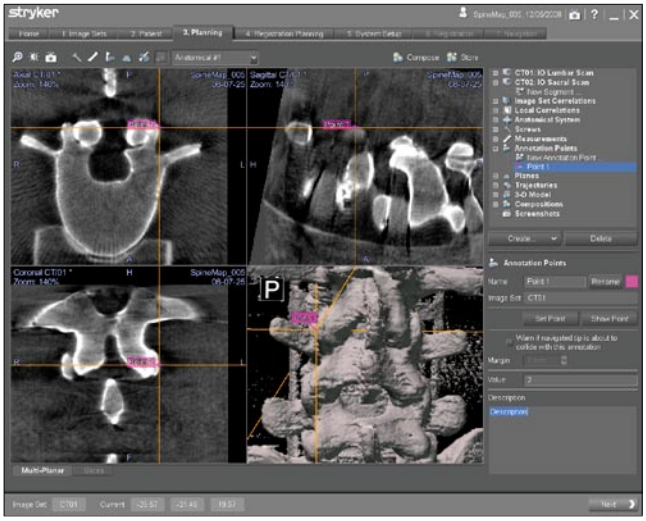
Annotation points creation

Step 1: Activate tool panel

1. Select the image set in which an annotation point is to be defined by clicking the image set item in the patient record tree.
2. Double-click **Annotation Points** and select **New Annotation Point**. The **Annotation Points** tool panel is displayed.







Step 2: Define annotation point

1. Set the cross-hair cursor on the landmark or area of interest to be annotated.
2. Select the **Set Point** button to record.

If required:

- Rename and add values or descriptions to the annotation point.

Note

The **Value** and **Description** fields can be used for any purpose. The information stored in these fields has no further function in the software.

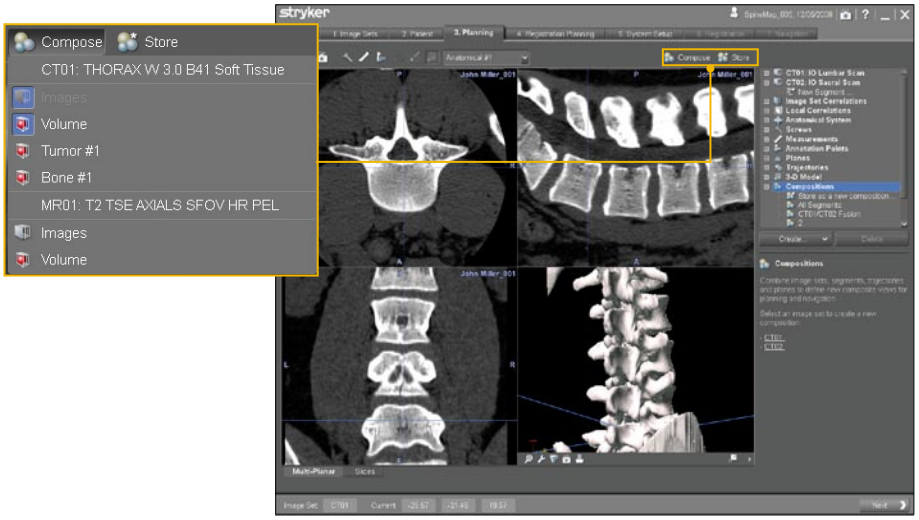
For each annotation point a safety margin can be defined. During navigation, the software warns surgeons visually and audibly as soon as the navigated tool tip enters this safety margin.

Click the icon to hide or display all annotation points.

Composition creation

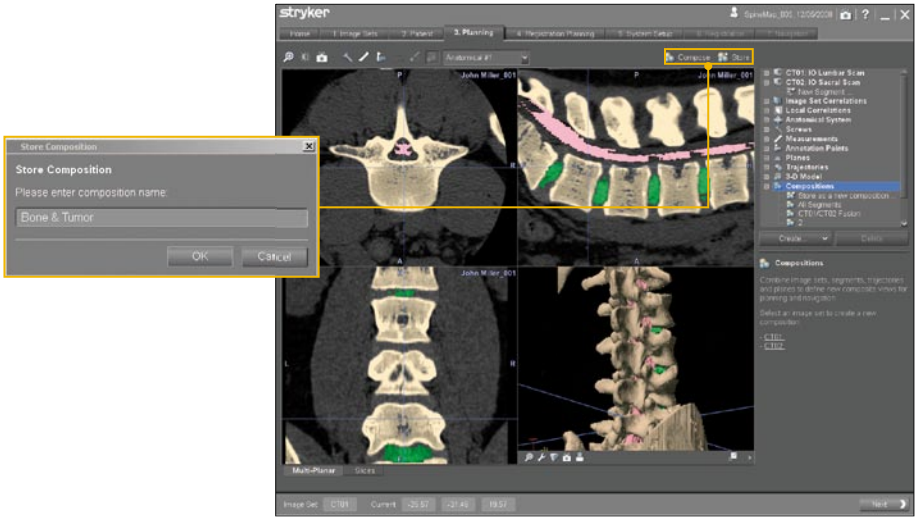
The compositions feature facilitates overlaying fused image sets, segments, trajectories and planes in a way most suited for the intended procedure. Created compositions can be recalled for navigation during surgery.

By default, the software automatically creates a composition named All segments that incorporates all segments, trajectories, planes and a fusion composition for each pair of correlated image sets.



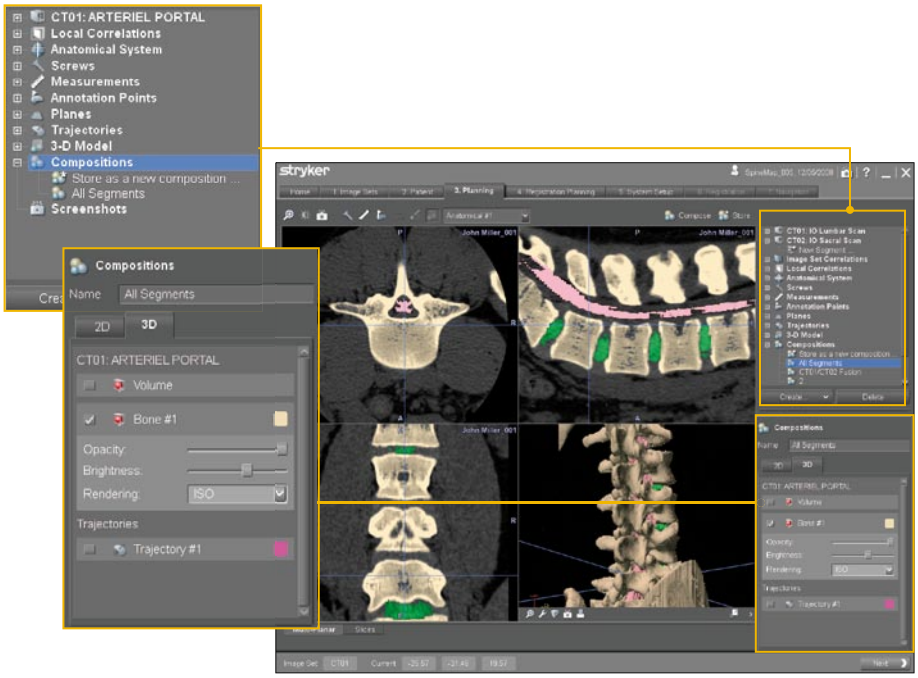
Step 1: Select image set and segment

- Click the **Compose** button and select the image sets and other items required for the image composition.



Step 2: Rename and store composition

1. Select the **Store** button and type in a composition name.
2. Select the **OK** button to confirm. Upon confirmation, the composition is stored and available for navigation.



Step 3: Adjust composition

The software enables a detailed adjustment of the intensity of the image sets and the opacity and brightness of the selected items.

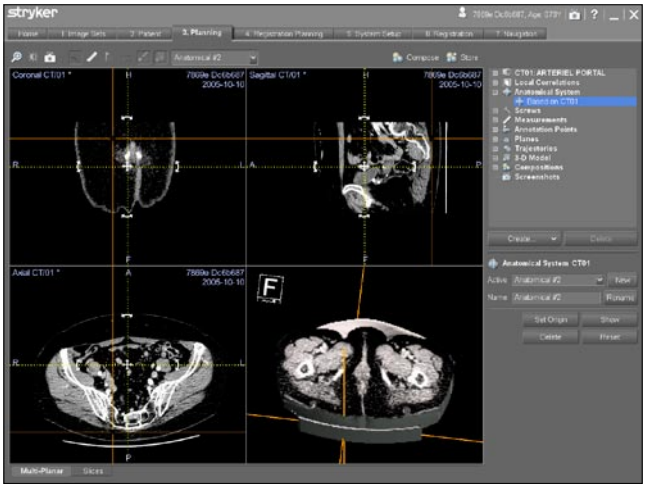
- Double-click **Compositions** in the patient record tree and select the desired composition.

In the **Compositions** tool panel:

- Select the **Change** button and change the weight of the fused image sets in the 2-D view (available only from the 2-D tab).
- Deselect image sets and other items from the 2-D or 3-D view.
- Change the selected item's opacity in the 2-D and 3-D view.
- Change the selected item's brightness in the 3-D view (available only from the 3-D tab).

Anatomical system creation

The anatomical system feature provides the possibility to create multiple anatomical systems per each series.

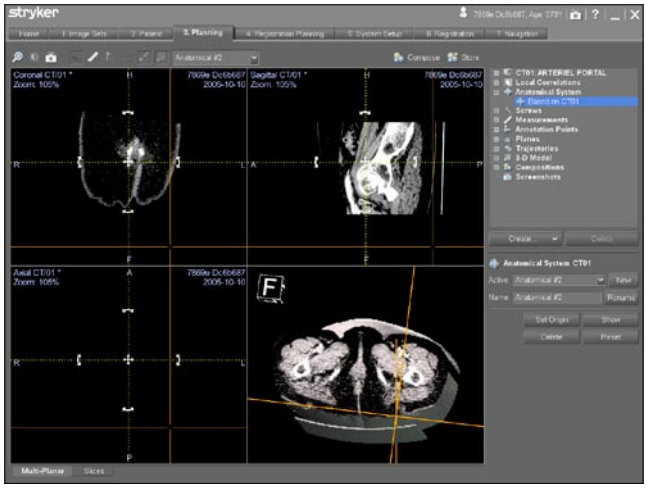


Step 1: Select image set

- Click the **New** button and select the required image set.

Step 2: Rename and store anatomical system

1. Type in a anatomical system name.
2. Click the **Rename** button.



Step 3: Adjust anatomical system

The software allows the current position of the cursor to be taken as the center point of the anatomical system.

1. Set the cursor to the desired position and click **Set Origin** to set the center point of the anatomical system.
2. Click and move the arrows in the 2-D views to adjust the anatomical system.

Reset and delete anatomical system

- Click the **Reset** button to set the anatomical system back to the initial status.
- Click the **Delete** button to delete the current anatomical system.

Note

All anatomical systems created by the user can be deleted.

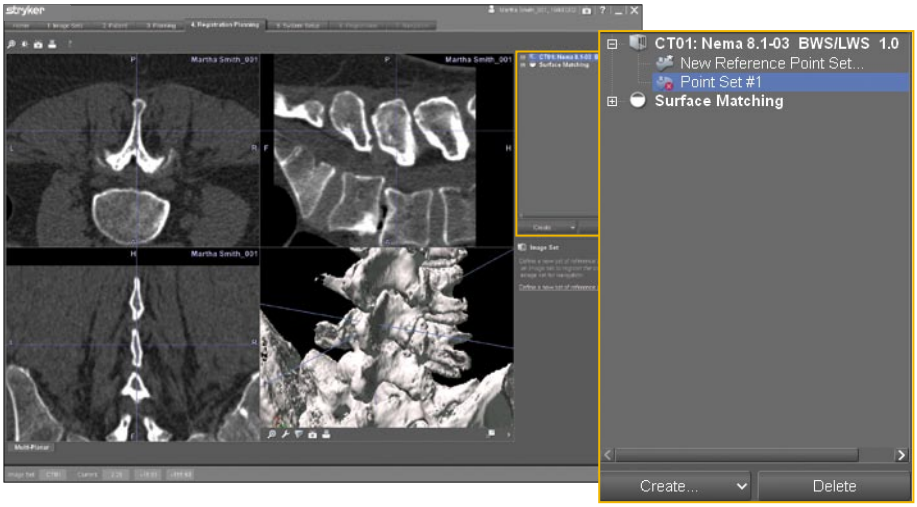
6. Registration Planning

Image based navigation requires to correlate the image series and the patient's anatomy. This process is called registration. The mandatory point registration planning process requires the definition of reference point sets on the CT base image series.

Point registration planning - overview

Step 1: Tool Panel Activation

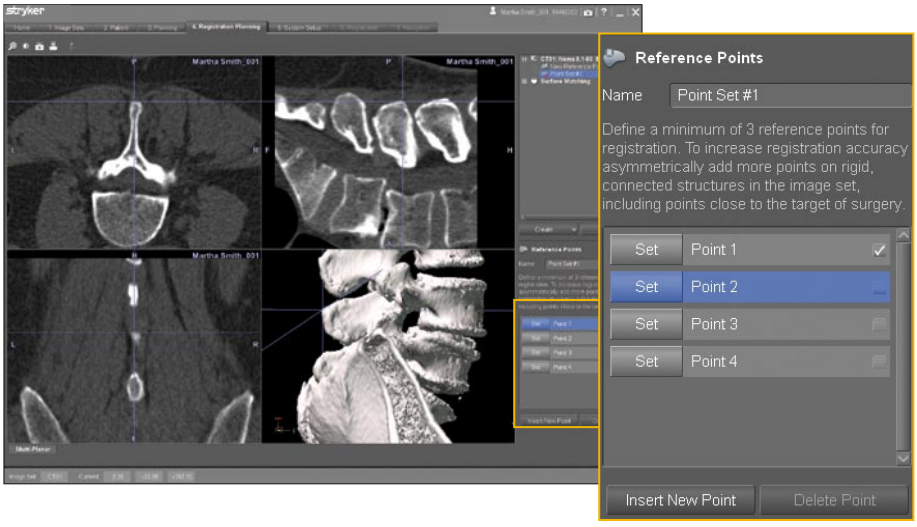
- In the Patient Record Tree View, double-click the CT base image series and select the **New Reference Point Set** item.
- Upon selection, the **Reference Points** Tool Panel appears.

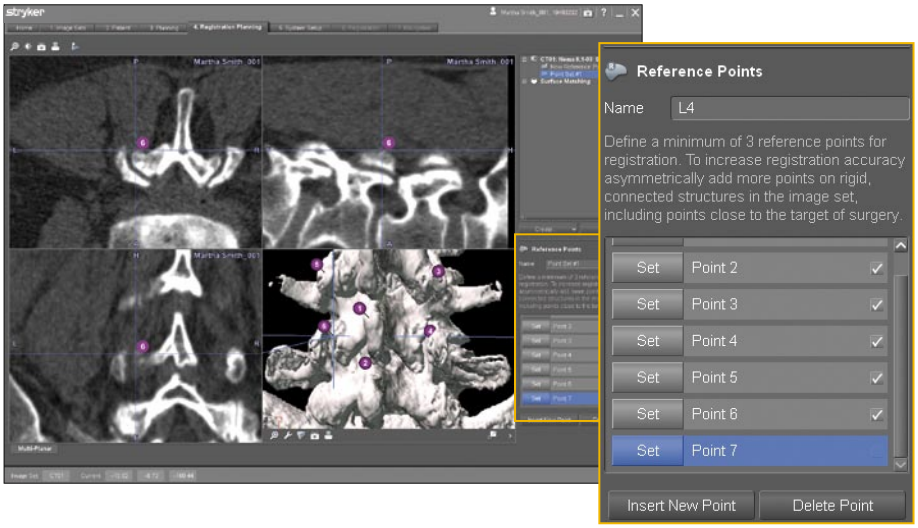


Step 2:

Reference Point Definition

1. Determine the first vertebra to be instrumented.
2. Set the cross-hair cursor on a distinct anatomical landmark of this vertebra. The landmark should be be easily identifiable on both the patient's images and the patient's anatomy and reachable with the tip of the awl during surgery.
3. Click the **Set** button to select the landmark as reference point.
4. Digitize a minimum of three to four additional landmarks on this vertebra. Make sure that the digitized points are distributed non-linear.


Reference Points
Name
Point Set #1
Define a minimum of 3 reference points for registration. To increase registration accuracy asymmetrically add more points on rigid, connected structures in the image set, including points close to the target of surgery.
Set
Point 1
Set
Point 2
Set
Point 3
Set
Point 4
Insert New Point
Delete Point



After reference point set definition for one vertebra is complete, it is recommended to rename the reference point set in accordance with the anatomical level (for example L4).

- Define additional reference point sets for each vertebra to be instrumented. Start definition of an additional set by selecting the item **New Reference Point Set** underneath the CT base image series link.

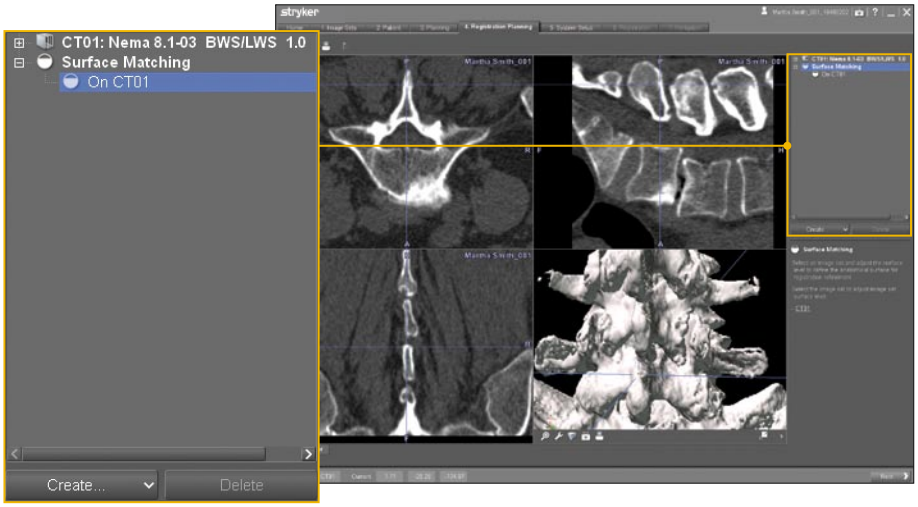
The following landmarks are commonly used as registration points:

- Most cranial and caudal points of the spinous process
- Facet joints

Surface matching planning - overview

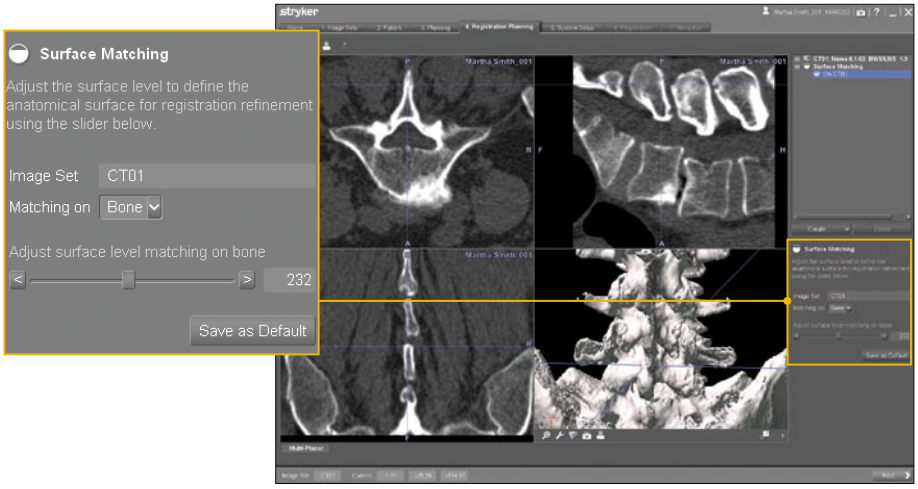
Surface matching facilitates to improve the accuracy of the initial mandatory point registration.

The surface matching process requires a well defined surface level of the 3-D CT image. The 3-D CT image must match the bony surface of the patient's anatomy as exactly as possible.



Step 1: Activate tool panel

1. Double-click the **Surface Matching** item and select the CT base image series listed underneath.
2. Upon selection, the **Define Matching Surface** Tool Panel appears.

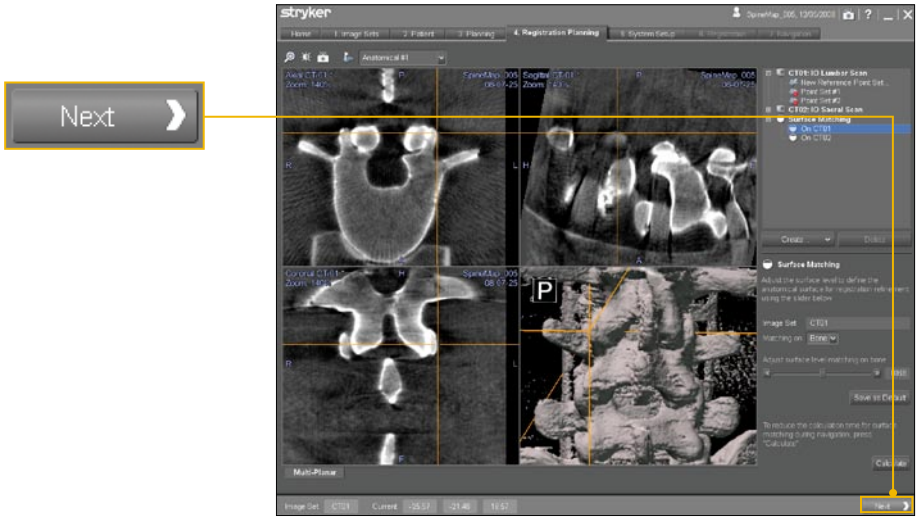


Step 2: Surface Definition

1. Select **Bone** as the surface on which the matching is to be done.
2. Use the slider to optimize the 3-D image display of the bony surface.

Note

For 3-D image optimization it is recommended to first increase the surface level until noise appears above the bony structures of the 3-D image. Then to decrease the surface level until the noise disappears.



Note

By clicking the **Save as Default** button, the current surface level setting can be saved as default for further CT image series.

- Select the **Next** button to proceed.

7. Set Up System

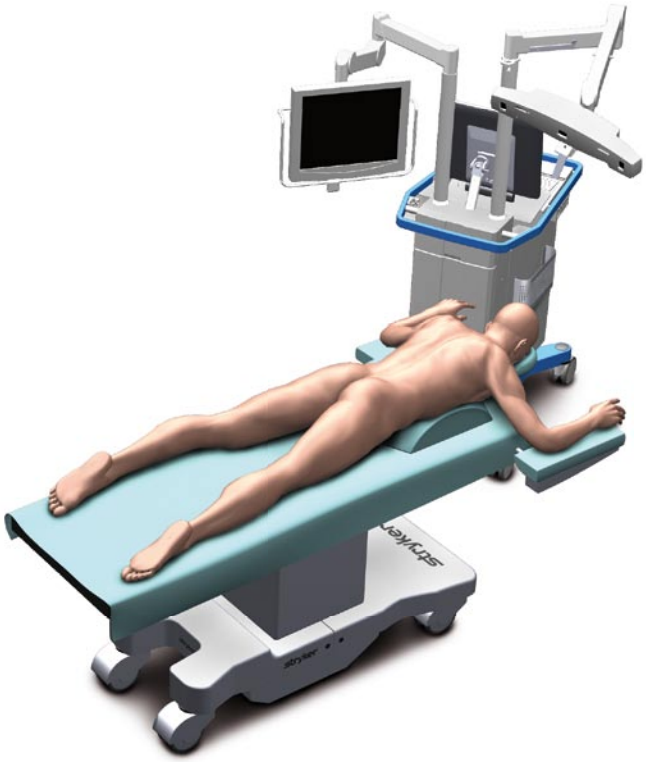
Position system

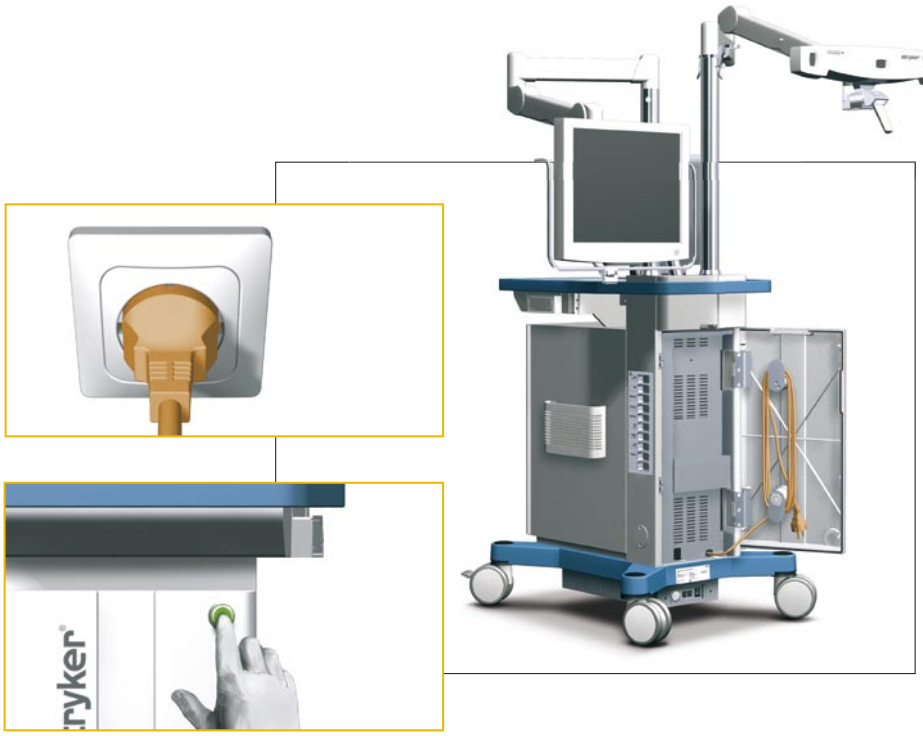
For navigated pedicle screw insertion with posterior approach and patient in prone position, the system is commonly placed at foot or head of the OR table.

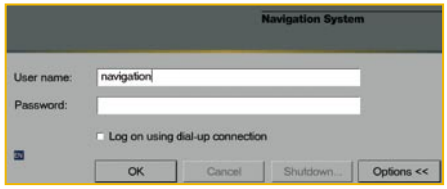
Depending on the situation in the OR, the approach and the type of surgery, other system positions are supported.

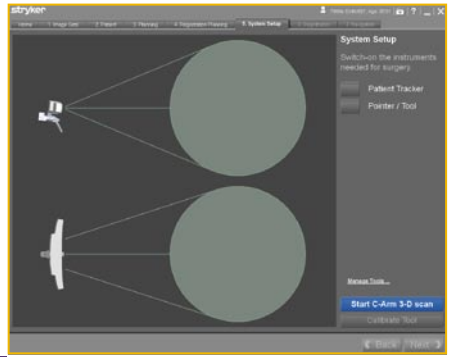
Independently of the system position, it is recommended to:

- Position the camera 1.65 m/ 5.5 feet away, facing towards the working area.









Start up system

1. Plug in the main power cable of the navigation system.

To boot the system:

2. Press the main power button on the front panel of the navigation system.

To log in:

3. Enter the **user name** (navigation) and press the **Enter** key or use the left mouse button and click the **OK** button.

To start the SpineMap 3-D navigation software:

4. Use the mouse to select the **SpineMap 3-D** button from the Application Manager.

If all mandatory pre-operative image import and planning tasks have already been completed:

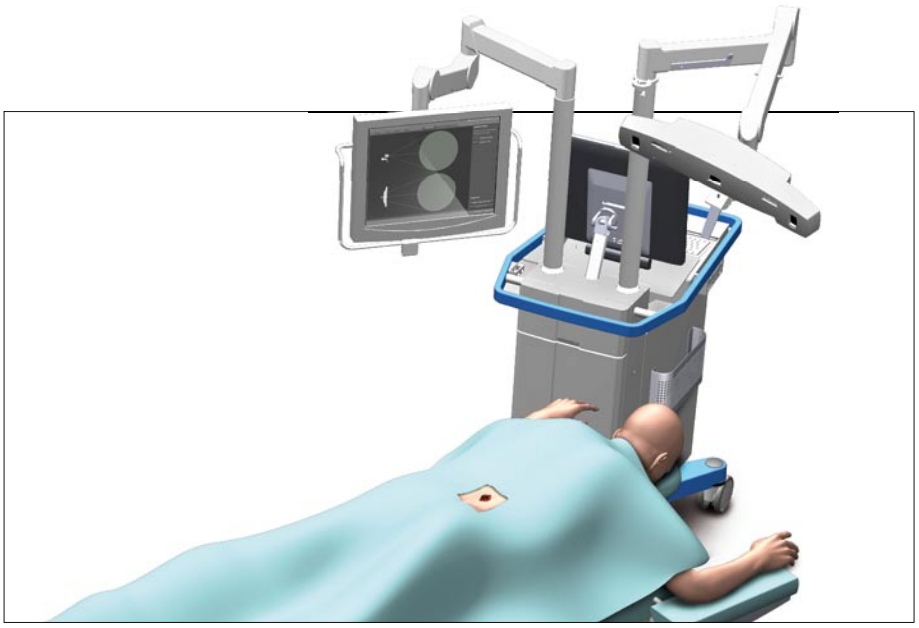
5. Select the desired patient from the section Ready for surgery on the Home page.

Upon selection, the System Setup dialog will be initialized automatically.

If image import and planning is still required:

- ▶ Proceed with Image Sets.

8. Registration

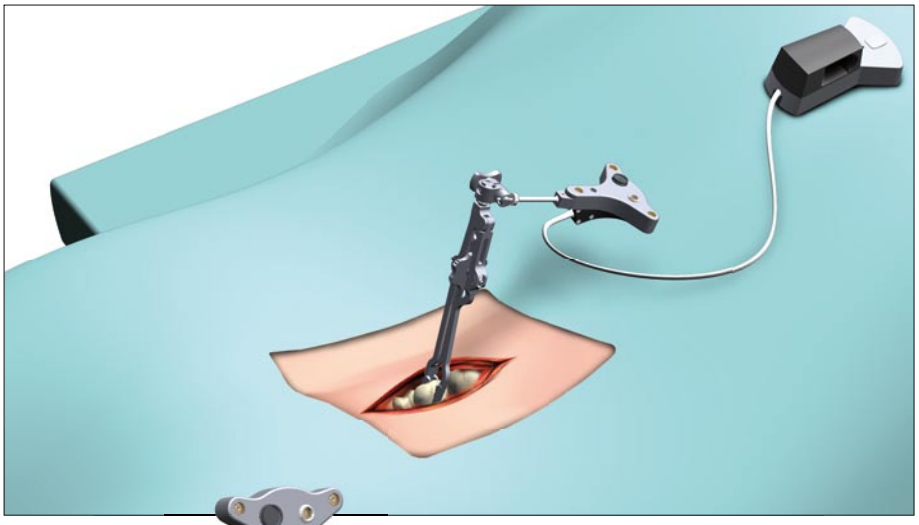


Prepare Patient

For intraoperative registration, a Patient Tracker must be fixated to the spinous process. After Spine Tracker fixation, dedicated instruments have to be initialized. In order to correlate the images with the patient's anatomy, the registration points defined during registration planning have to be digitized at the site of operation.

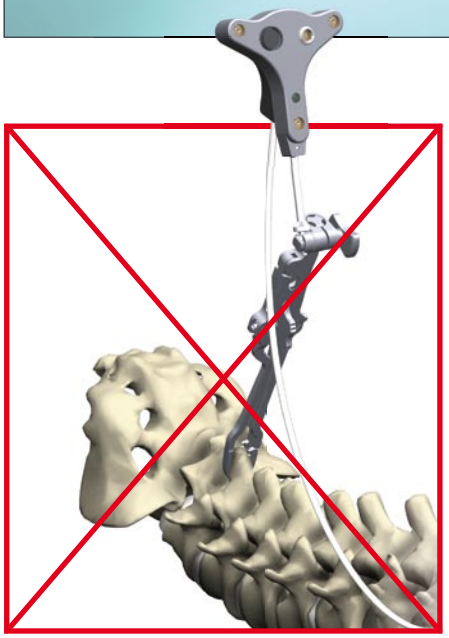
Step 1: Position patient, prepare patient and Incision

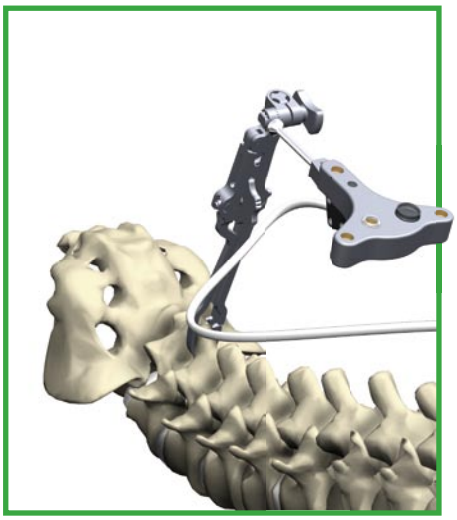
1. Position and prepare the patient in accordance with the standard protocol.
2. Verify the surgical levels clinically or radiographically and make the incision, ensuring adequate exposure.



Step 2: Fixate spine clamp and spine tracker

1. Fixate the Spine Clamp firmly onto the spinous process of the vertebra that will be registered and instrumented first.
2. Attach the Spine Tracker onto the Spine Clamp and align it line of sight to the camera.
3. Verify the stability of the connection between the Spine Clamp and the spinous process again.





When attaching and aligning the Spine Tracker:

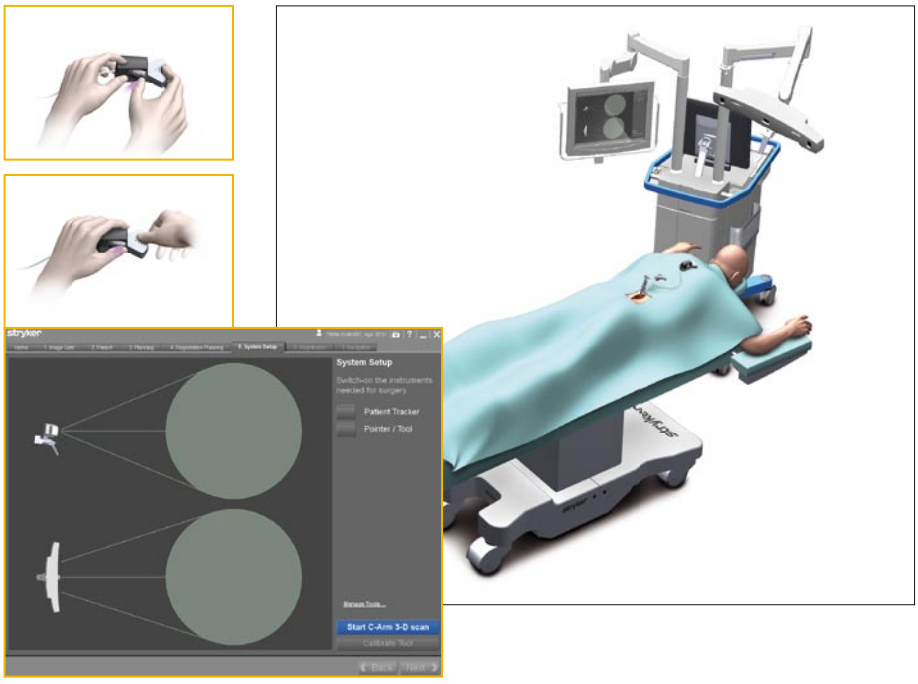
- Ensure that the Spine Tracker set up is not a "tower formation". The Spine Tracker should be turned down towards the patient's back.
- Ensure that the LEDs of the Spine Tracker are facing towards the camera.

Set up system

The S**ystem Setup** Dialog requests the initialization of sterile tools for the registration process. The following tools are recommended:

- Spine Tracker
- Vector Calibration Device (VCD)
- Navigated Awl

Instead of the Navigated Awl, a Long Pointer can be used.



Step 1: Initialize spine tracker, VCD and navigated awl

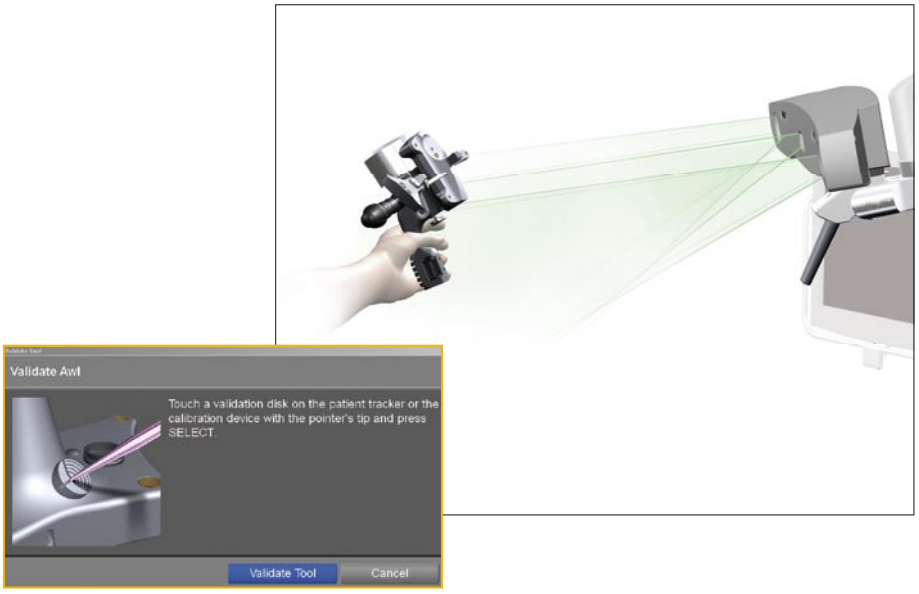
1. Load a sterile battery into the battery housing of the Spine Tracker.
2. Make sure that the LEDs of the Spine Tracker face towards the camera and press and hold the battery housing's **SELECT** button to initialize.
3. Repeat battery insertion and tool initialization for the sterile VCD and the sterile Navigtated Awl.

The initialization of any tool is confirmed by an audible chime and a check mark in front of the software button.

Step 2: Validate navigated awl

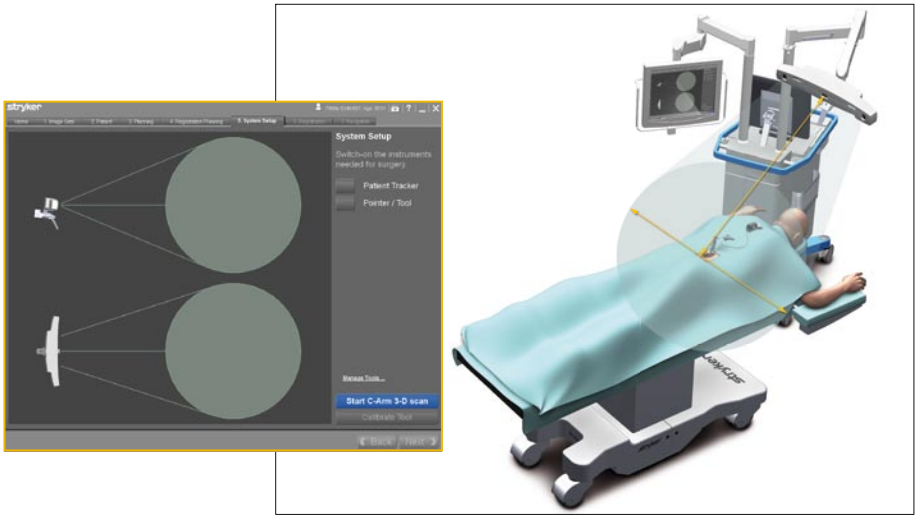
Upon initialization of the Navigated Awl, the V**alidate Tool** Window appears on the screen.

- Touch the center of one of the VCD's validation disks with the tip of the awl and press the awl's **SELECT** button to confirm.


Validate Awl
Touch a validation disk on the patient tracker or the calibration device with the pointer's tip and press SELECT.
Validate Tool
Cancel

Step 3: Align camera

1. Align the camera in such a way that the Spine Tracker is visible and in the center of the camera's working space.
2. Click the **Next** button to proceed with point registration.



Point registration - overview

Step 1: Select reference point set

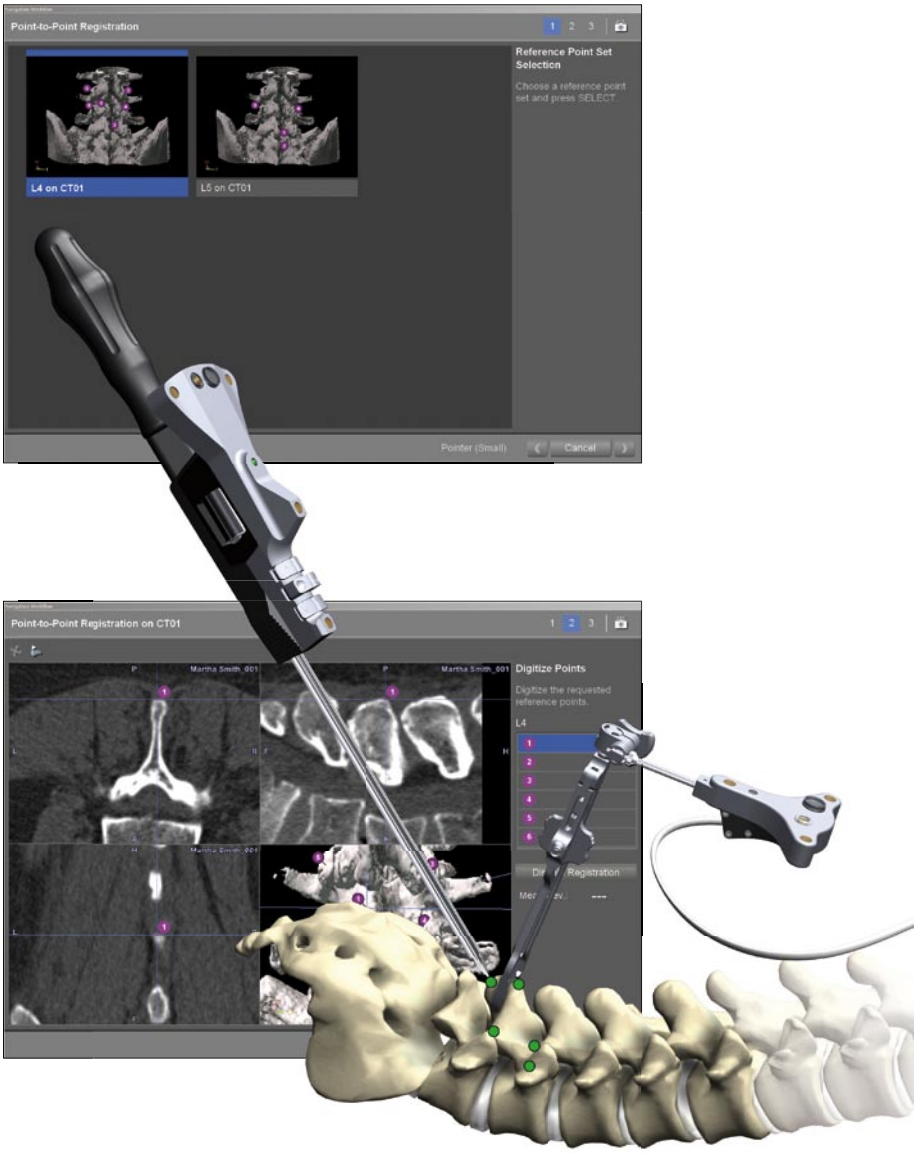
1. Highlight and select the reference point set defined for the vertebra where the Spine Tracker is currently attached by using the awl's control buttons.
2. Upon selection, the **Digitize Points** Tool Panel is activated.

Step 2: Point Digitization

1. Place the tip of the awl onto the vertebral landmark displayed as registration point by the software and press the awl's **SELECT** button to digitize.
2. Upon successful digitization, the reference point number is checked.
3. Digitize the remaining registration points.
4. Click the **Enable Registration** button to activate registration.

Upon completion:

- Highlight and select the > button to proceed with point registration confirmation (Step 3).



Step 3: Confirm point registration

To verify the registration accuracy:

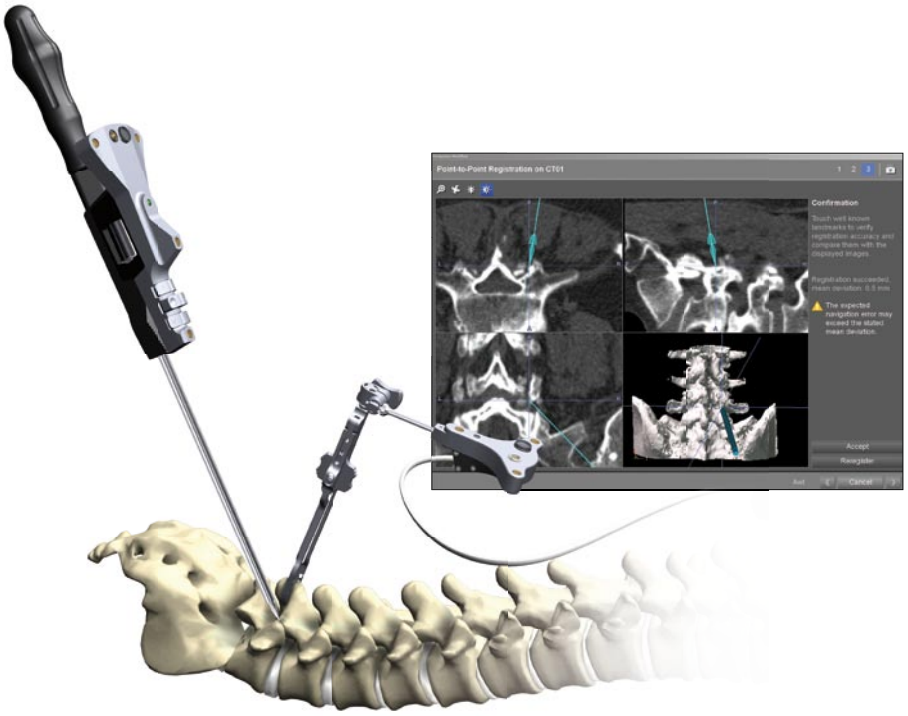
1. Touch distinct anatomical landmarks with the awl's tip.
2. Compare the actual tip location with the reported location on the images.

If the accuracy is satisfactory in order to navigate or acceptable as initial registration followed by surface matching:

3. Highlight and confirm **Accept.**

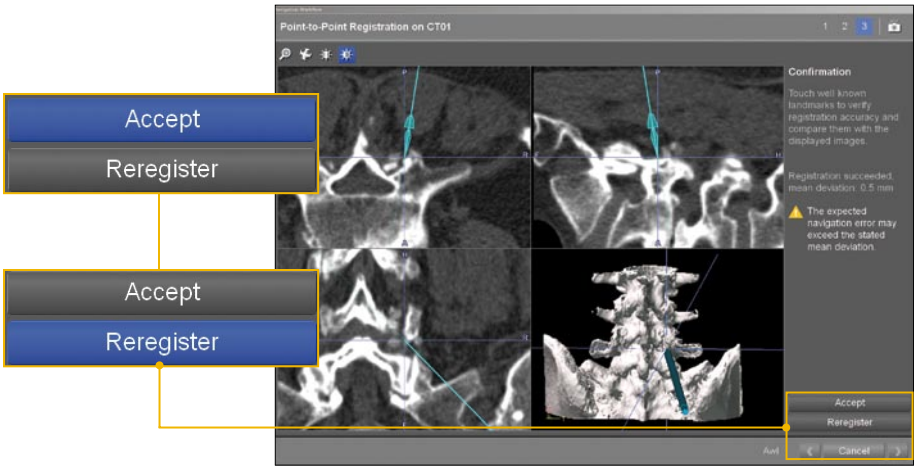
If required:

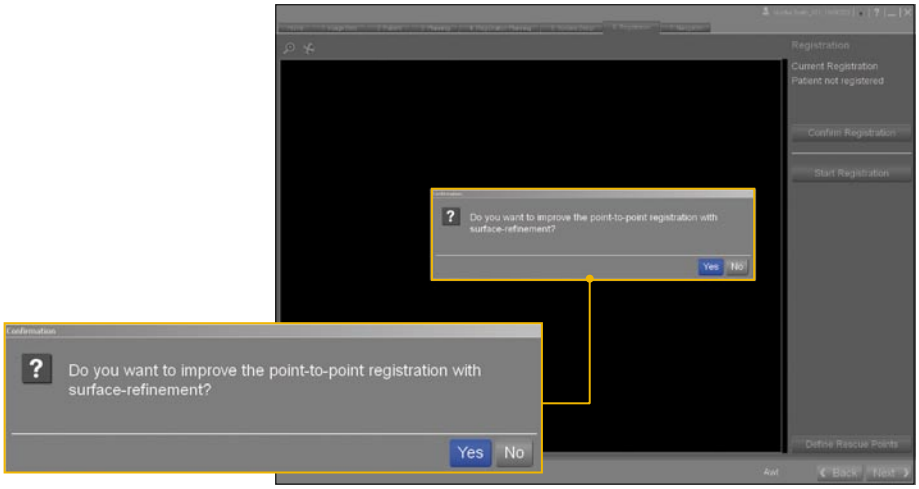
- Highlight and select the **Reregister** button.
- Repeat point digitization (Step 2) and point registration confirmation (Step 3).



⚠ Caution

Always confirm registration accuracy by using multiple landmark tests. The surgeon must be comfortable with the accuracy before proceeding.





Step 4: Select surface refinement

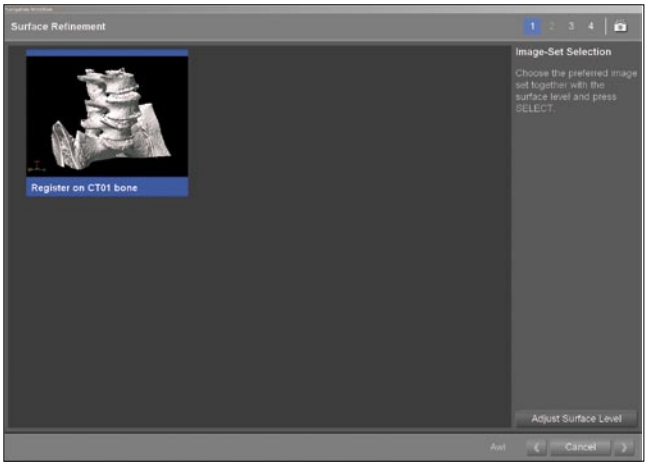
Surface refinement (surface matching) is recommended in order to improve registration accuracy.

To proceed with surface refinement:

- Confirm **Yes** by using the awl's **SELECT** button.

Surface matching - overview

Surface matching (surface refinement) is an additional registration option. Surface matching can be selected after the inital point registration process is completed. With surface matching, the accuracy of the initial point registration can be improved.



Step 1: Select image set

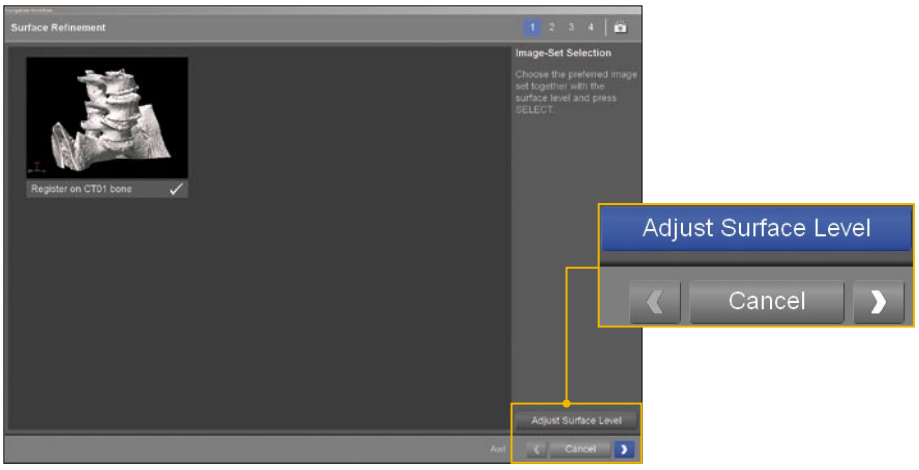
- Select the CT base image series with bone surface by using the awl's control buttons.

Step 2: Adjust surface level (optional)

- Make sure that the displayed 3-D image matches the bony surface of the spinal column.

If required:

- Hightlight and confirm the **Adjust Surface Level** button.

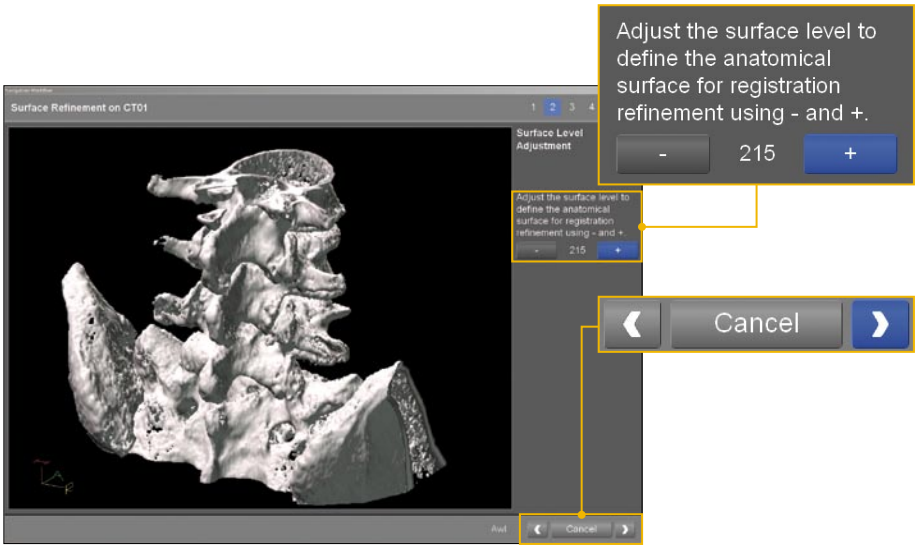


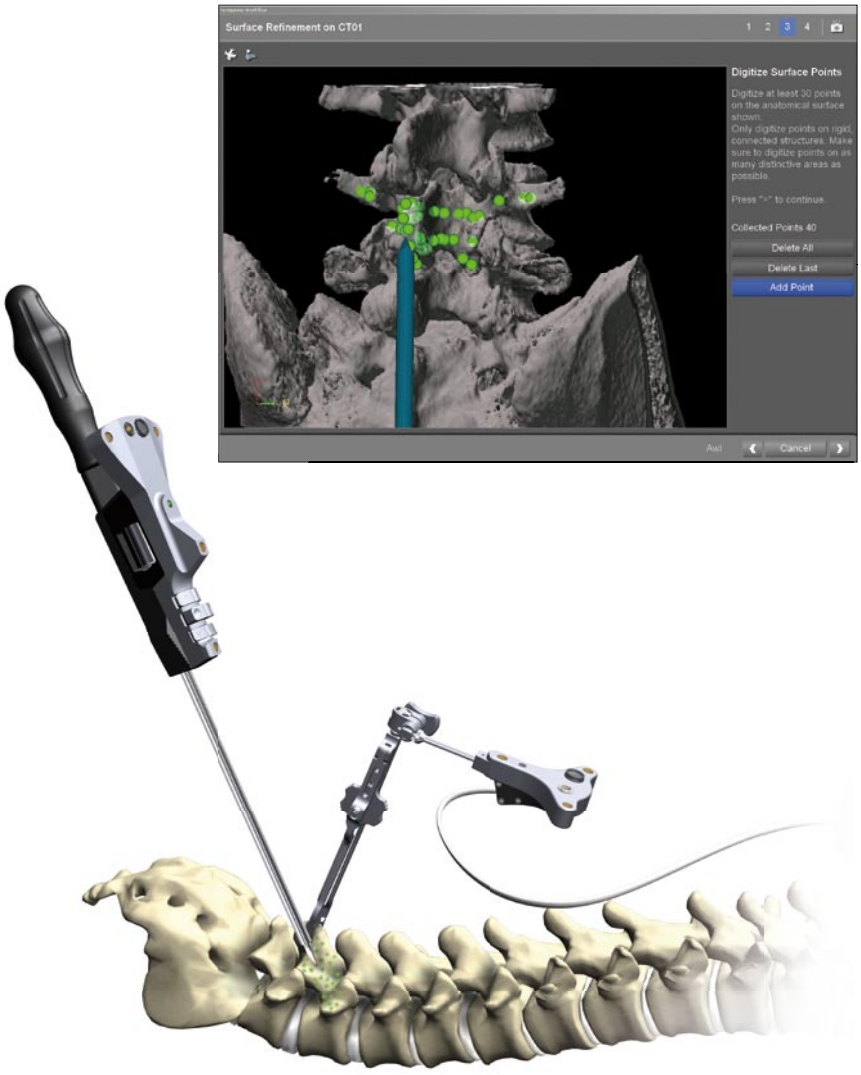
To adjust the surface level:

- Hightlight and select the + or the - button.

Upon completion:

- Highlight and select the > button to proceed with surface point digitization (Step 3).




Surface Refinement on CT01
1 2 3 4
Digitize Surface Points
Digitize at least 30 points on the anatomical surface shown.
Only digitize points on rigid, connected structures. Make sure to digitize points on as many distinctive areas as possible.
Press ">" to continue.
Collected Points 40
Delete All
Delete Last
Add Point
Axial
Cancel

Step 3: Digitize surface point

1. Make sure that the **Add Point** button is highlighted.
2. Move the tip of the awl along the surface of the vertebra on which the initial point registration was performed and press the awl's **SELECT** button repeatedly.
3. Digitize at least 30 points. Ensure that:
   - The points cover prominent areas such as spinous process, articular processes and transverse processes.
   - The points only cover the vertebra with the Spine Tracker attached to and are spreaded out across all three dimensions.

After a sufficient number of points are digitized:

▶ Highlight and select the > button to start surface matching.

Step 4: Confirm surface matching

Surface Refinement on CT01
1 2 3 4
Confirmation
Touch well known landmarks to verify registration accuracy and compare them with the displayed images.
Registration succeeded.
37 of 40 points used.
mean deviation: 0.6 mm
The expected navigation error may exceed the stated mean deviation.
Accept
Reregister
Axl
Cancel

To verify the registration accuracy:

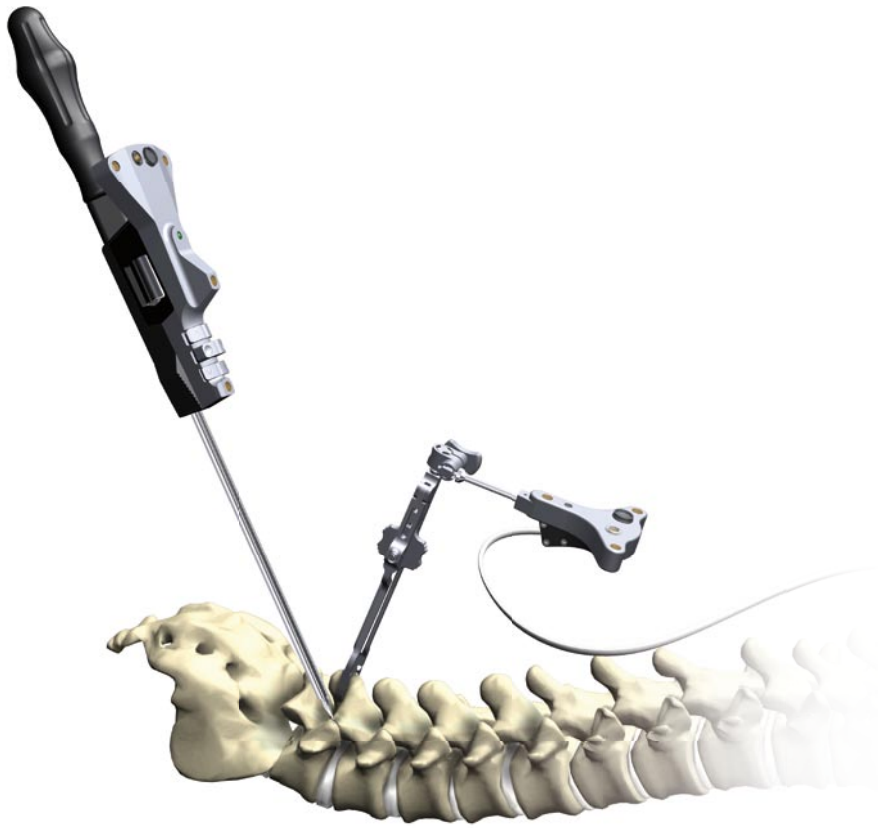
1. Touch distinct landmarks of the registered vertebra with the awls's tip.
2. Compare the actual tip location with the reported location on the images.

If the accuracy is satisfactory:

3. Make sure that the **Accept** button is highlighted.
4. Press the awl's **SELECT** button to confirm and to proceed with the surgery.

If required:

5. Use the awl's control buttons to highlight and select the **Reregister** button.
6. Repeat surface point digitization (Step 3) and surface matching confirmation (Step 4).



⚠ Caution

Always confirm registration accuracy by using multiple landmark tests. The surgeon must be comfortable with the accuracy before proceeding.

If one or several of the points appears red, then that point was not registered on the surface level and therefore was rejected by the system and is not included in the surface matching.

9. Pedicle Screw Navigation

Pedicle screw navigation - preoperative checklist

System startup	❑ Plug in the Navigation System, turn it on and log in and start the SpineMap 3-D application.
Import image sets	❑ Select **Start new case** and select the CT base image set. ❑ Verify the CT image set and import the images.
Patient	❑ Select the features required for surgical planning. If required: ❑ Change or add patient data.
Planning (optional)	If desired: ❑ Use any of the planning tools for surgery planning.
Registration planning	For point registration: ❑ Define one reference set for each vertebra to be instrumented. For surface matching: ❑ Define the matching surface.
System setup	❑ Position the system and align the camera. ❑ Position and prepare the patient. If the system was shut down after planning: ❑ Repeat the system startup and select the patient entry in the Ready for surgery section on the Home page. ❑ Initialize the tools requested by the software.
Registration	For point registration: ❑ Digitize the reference points. If required: ❑ Perform surface matching to improve the point registration.

Prepare entry point

⚠ **Caution**

For accuracy and the patient's safety, navigation should only be used for the registered vertebra.

Step 1: Select view (optional)

The Tool's Eye 3-D view is commonly used for pedicle screw navigation.

Tool's Eye 3-D view consists of three 2-D images reconstructed with respect to the tool axis (along 0°, along 90° and perpendicular to the tool axis) and one 3-D image.

- Select the desired view by using the awl's control buttons.

Step 2: Select composition (optional)

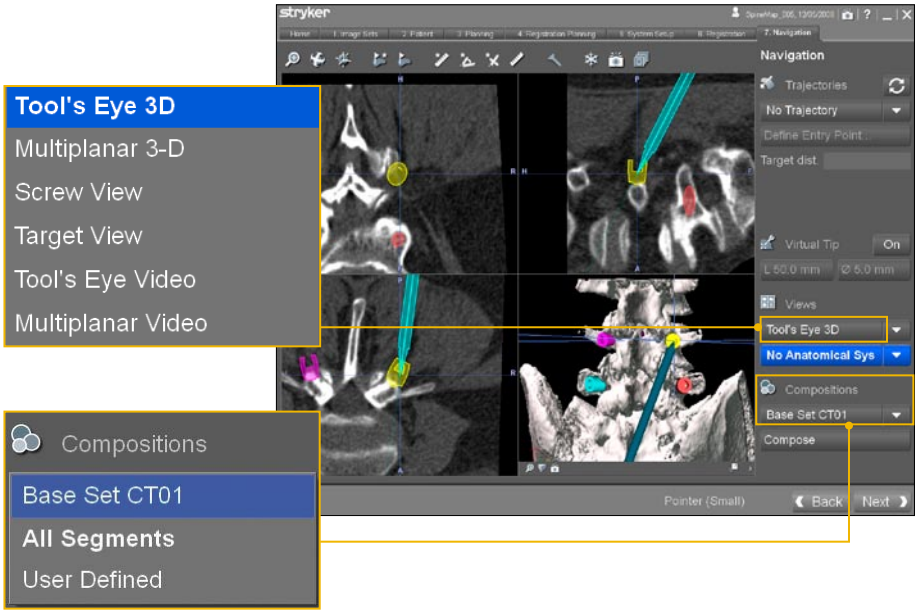
By default the CT base image set is active.

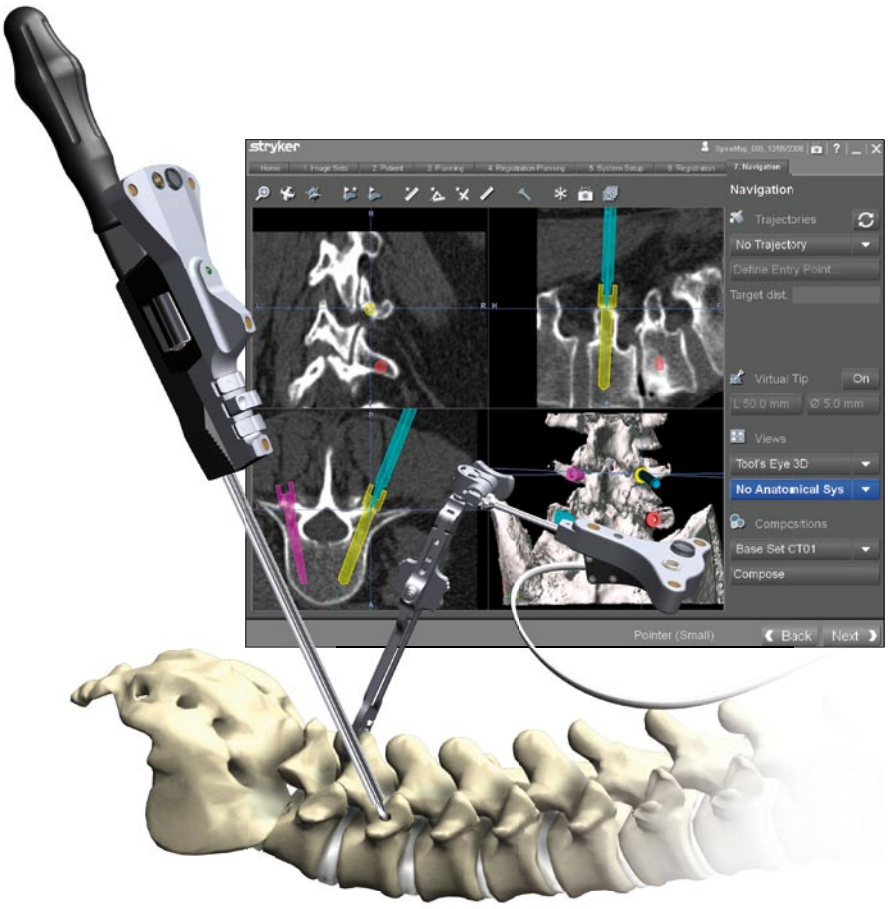
If required:

- Call up correlated image sets or an already planned composition by using the awl's control buttons.

Alternatively:

- Click the **Compose** button to create compostions on-the-fly by selecting any of the available fused images, segments, planes or trajectories (not illustrated).





Step 3: Prepare entry point

The entry point can be identified and prepared by using the awl.

By default, planned screws are displayed supporting efficient entry point identification and instrument alignment.

- The **Rotate-3-D** function (select the icon) can be used to point to an entry and to rotate the selected point to the front in the 3-D scene.
- The **Show/Hide Screw** function (select the icon) can be used to display or to hide all planned screws.

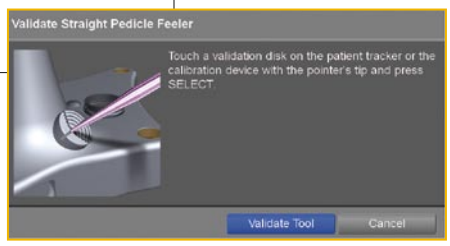
Open pedicle pathway

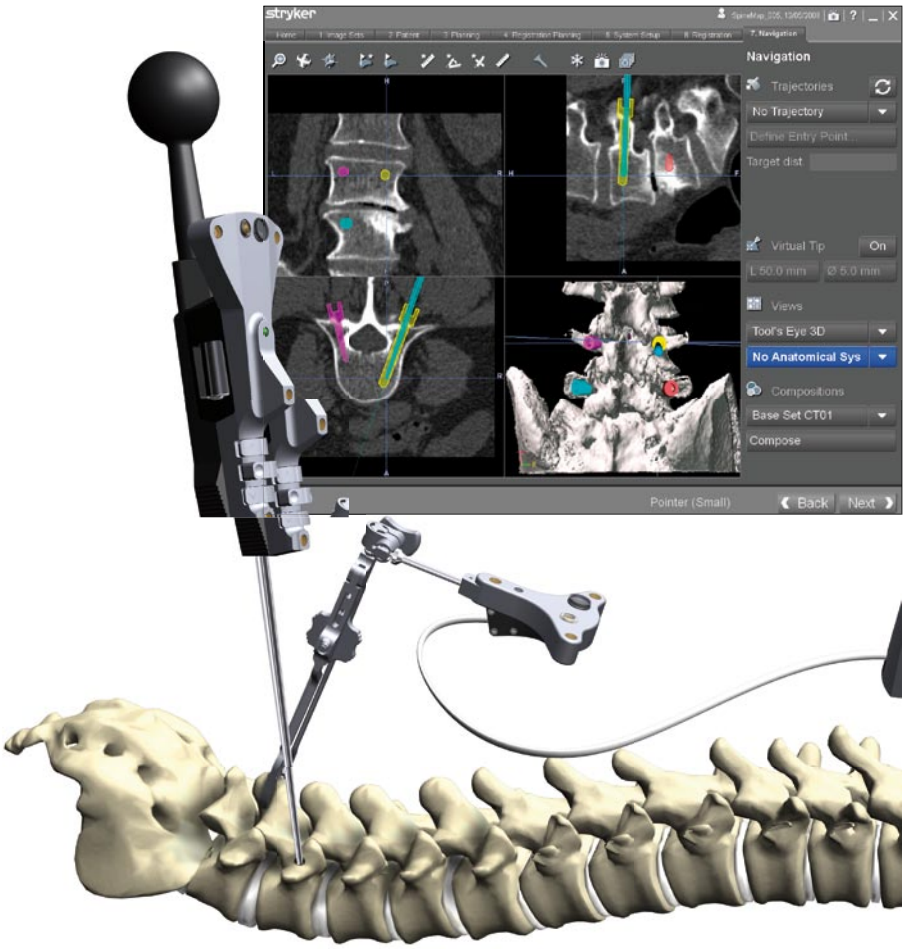
Step 1: Initialize tool

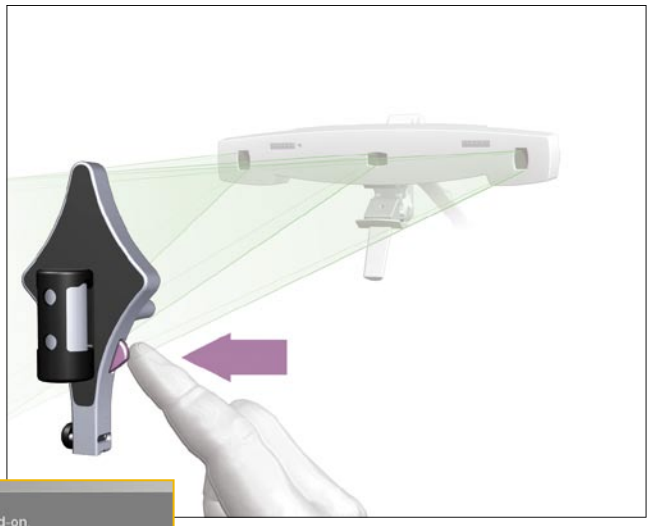
1. Insert a sterile battery into a sterile Navigated Pedicle Feeler.
2. Make sure that the pedicle feeler's LEDs face towards the camera and press and hold the **SELECT** button to initialize. Upon initialization, the V**alidate Straight Pedicle Feeler** Window is displayed.
3. Touch the center of any of the VCD's validation disks with the pedicle feeler's tip and press the **SELECT** button to confirm.

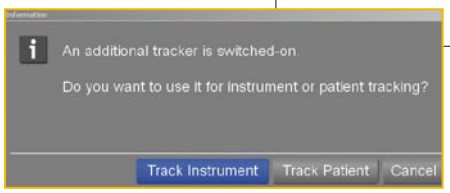
Step 2: Open pedicle pathway

A pathway can be opened by using the Navigated Pedicle Feeler.


Validate Straight Pedicle Feeler
Touch a validation disk on the patient tracker or the calibration device with the pointer's tip and press SELECT.
Validate Tool
Cancel






An additional tracker is switched-on.
Do you want to use it for instrument or patient tracking?
Track Instrument
Track Patient
Cancel

Integrate and calibrate conventional instrumentation exemplified by pedicle pathway preparation with a tap.

SpineMap 3-D software facilitates the integration of conventional instruments. For conventional instrument integration a NavLock adapter, a Universal Tracker and a calibration device are required.

Step 1: Prepare tool

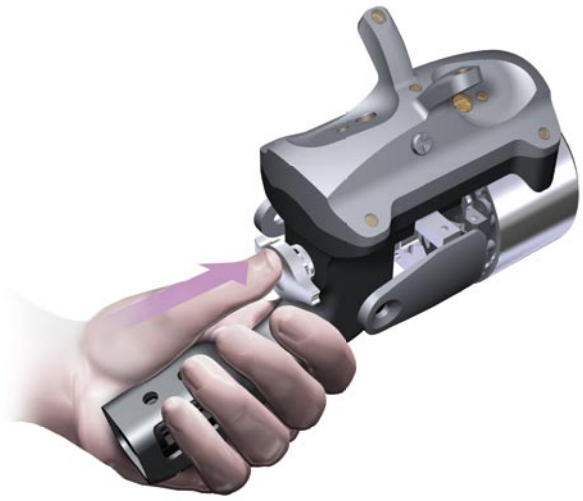
1. Select the required tap.
2. Mount a NavLock adapter onto the tap (not illustrated).
3. Attach a Universal Tracker onto the NavLock.
4. Insert a sterile battery into the Univeral Tracker (not illustrated).
5. Make sure that the Universal Tracker's LEDs face towards the camera and press and hold the tracker's **SELECT** button to initialize. Upon initialization, an information box appears.
6. Press the tracker's **SELECT** button to confirm Track Instrument. The **Calibrate Universal Tracker** Dialog starts.

Step 2: Initialize calibration device

1. Insert a sterile battery into the Vector Calibration Device VCD (not illustrated).
2. Make sure that the VCD's LEDs face towards the camera and press and hold the VCD's **SELECT** button to initialize.

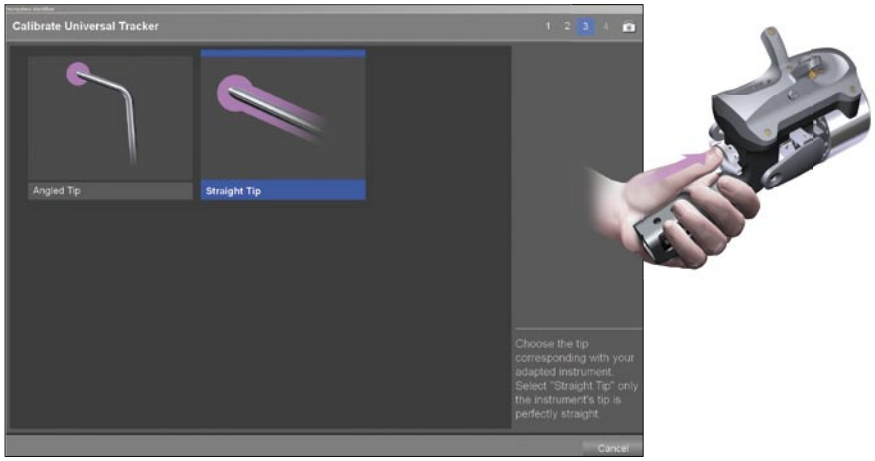
Note

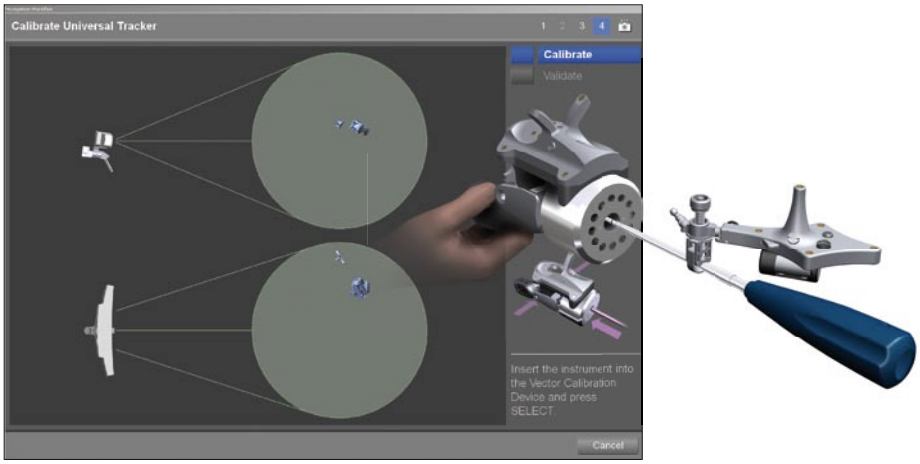
VCD initialization is only necessary if the Point Calibration Device (PCD) has been used for system set up. If the VCD has already been intialized and used, this step is automatically skipped by the software.

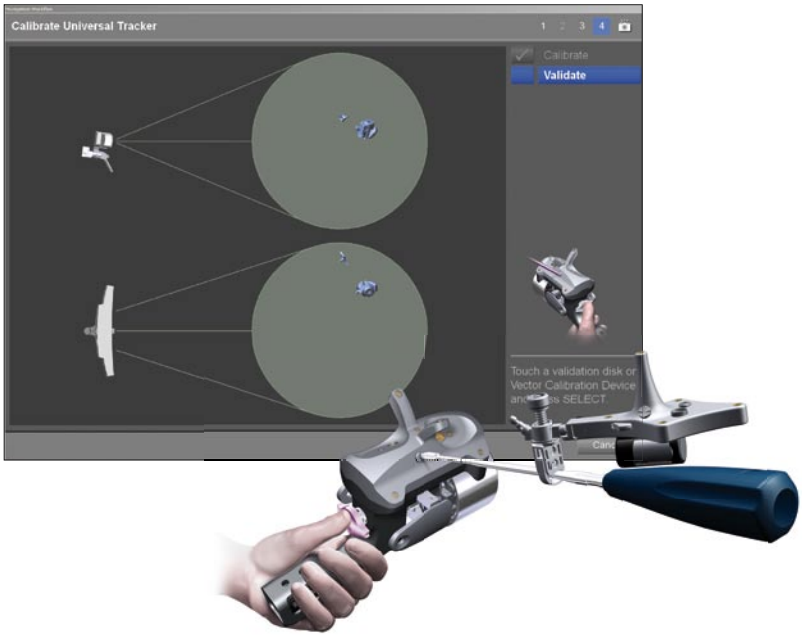


Step 3: Select adapter

- Highlight and select **Universal Adapter** by using the VCD's **SELECT** button.


Calibrate Universal Tracker
1 2 3 4
Angled Tip
Straight Tip
Choose the tip corresponding with your adapted instrument. Select "Straight Tip" only the instrument's tip is perfectly straight.
Cancel




Calibrate Universal Tracker
1 2 3 4
Calibrate
Validate
Touch a validation disk or Vector Calibration Device and press SELECT.

Step 4: Calibrate tap (straight tip)

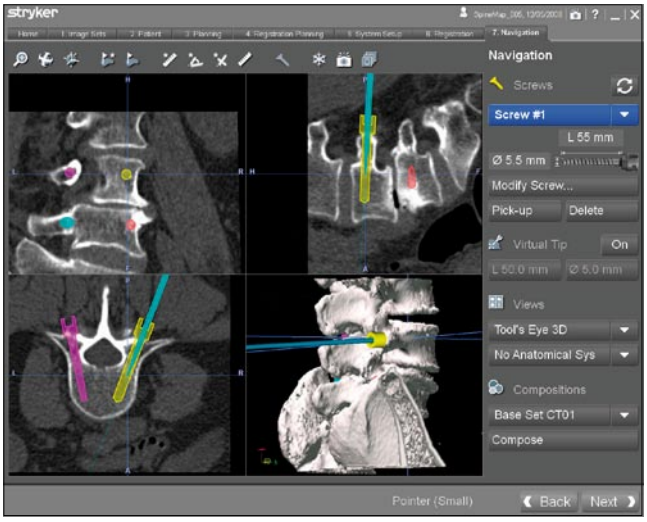
1. Make sure that **Straight Tip** is highlighted and press the VCD's **SELECT** button to confirm.
2. Insert the tap into the opening of the VCD as indicated. Make sure that the tap is centered and touches the base of the device.
3. Make sure that both tools are visible and centered in the working space of the camera.
4. Press the VCD's **SELECT** button to calibrate the tap (straight tip).

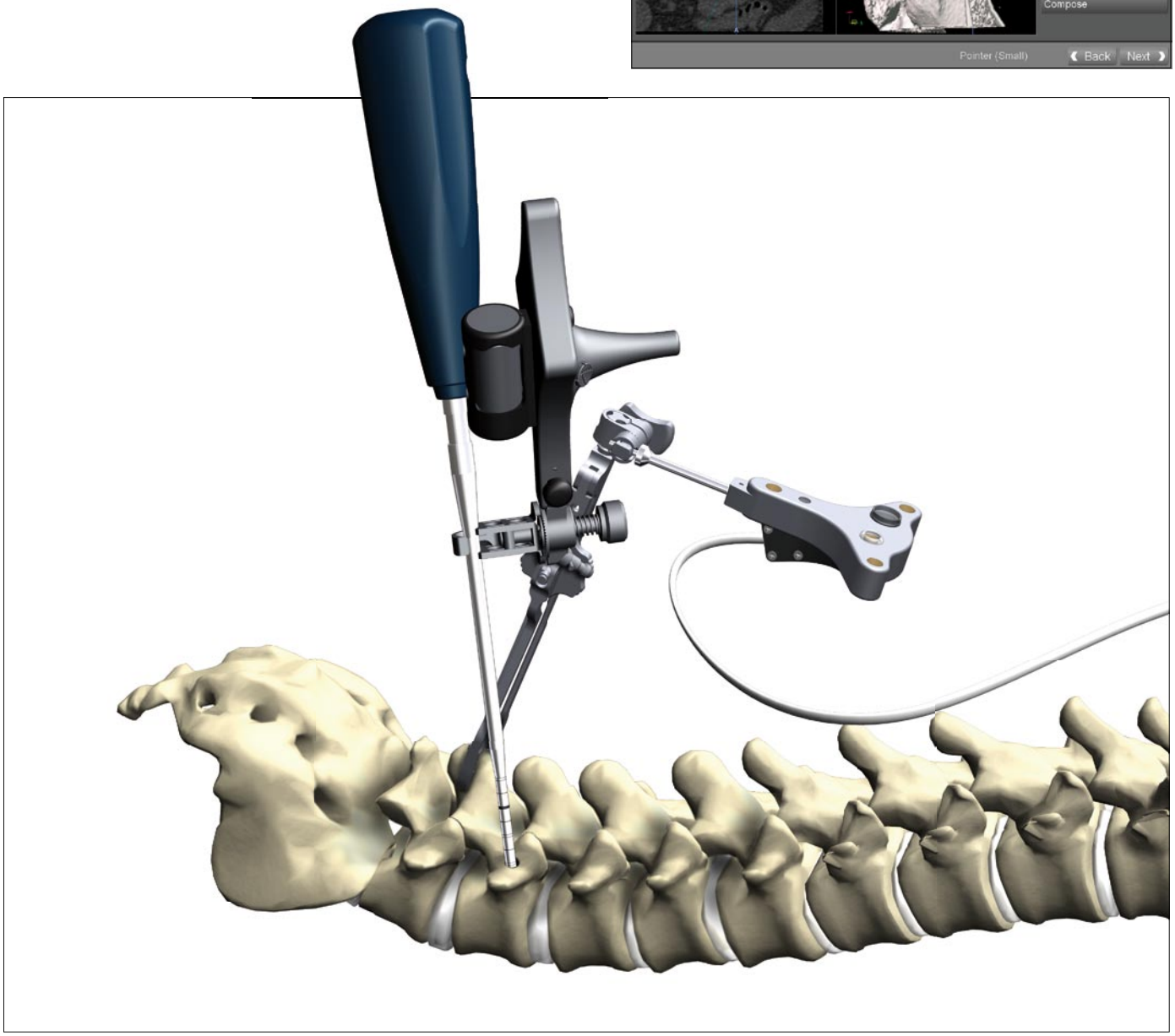
To verify the tap (straight tip) calibration:

5. Touch the center of any of the VCD's validation discs with tip of the tap and press the VCD's **SELECT** button to confirm.

Step 5: Prepare navigated pedicle pathway

With the calibrated tap, pedicle pathway preparation can be navigated.





10. Insert Pedicle Screw

After pedicle pathway preparation, the pedicle screw can be inserted.

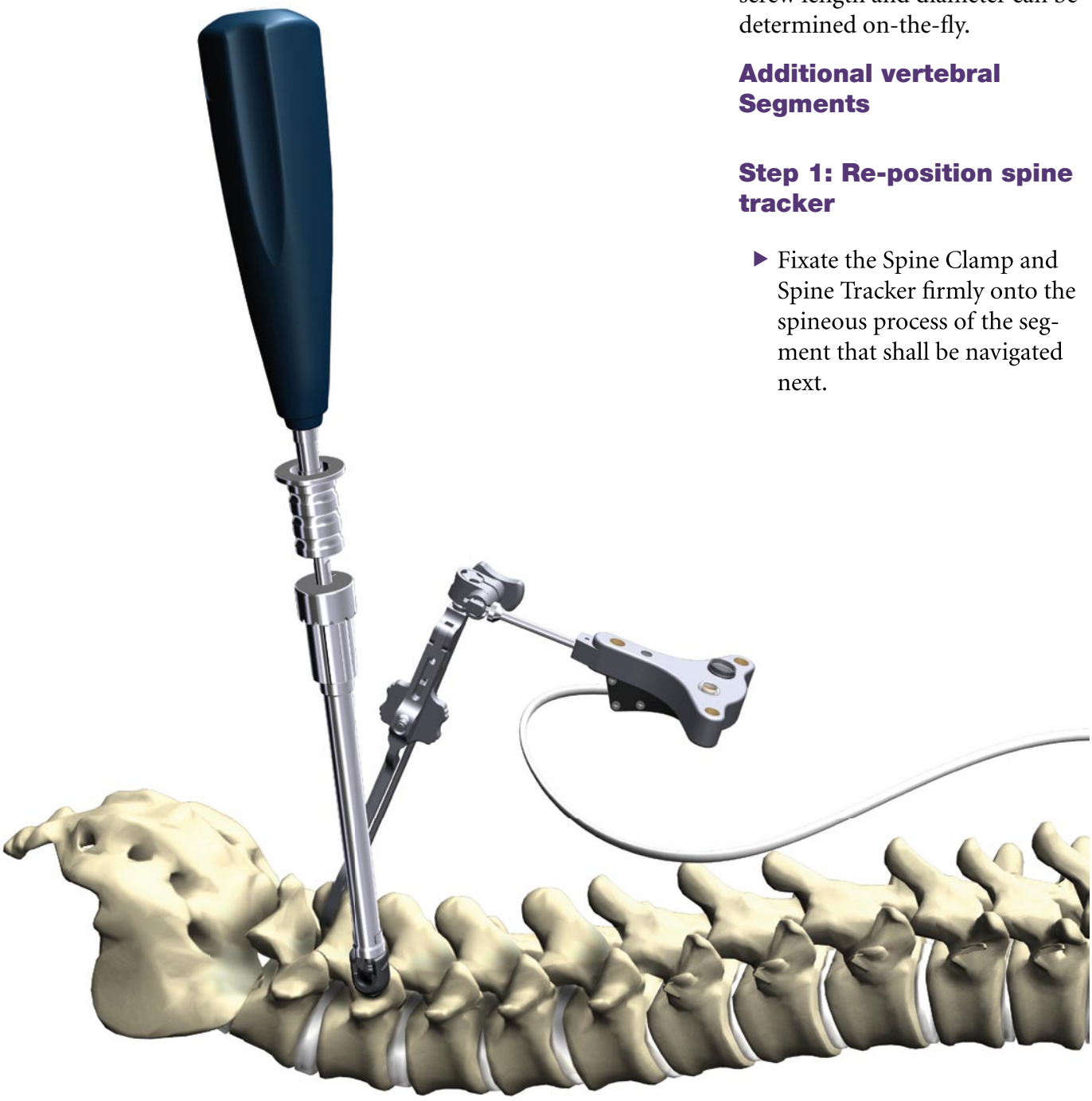
Note

If screws have not been planned, screw length and diameter can be determined on-the-fly.

Additional vertebral Segments

Step 1: Re-position spine tracker

- Fixate the Spine Clamp and Spine Tracker firmly onto the spineous process of the segment that shall be navigated next.



Step 2: Registrate

1. Select the **Back** button on the navigation screen.
2. Select **Start Registration** on the registration screen.
3. Select the reference point set for the segment where the Spine Tracker is currently attached.
4. Perform the registration.

Step 3: Navigate

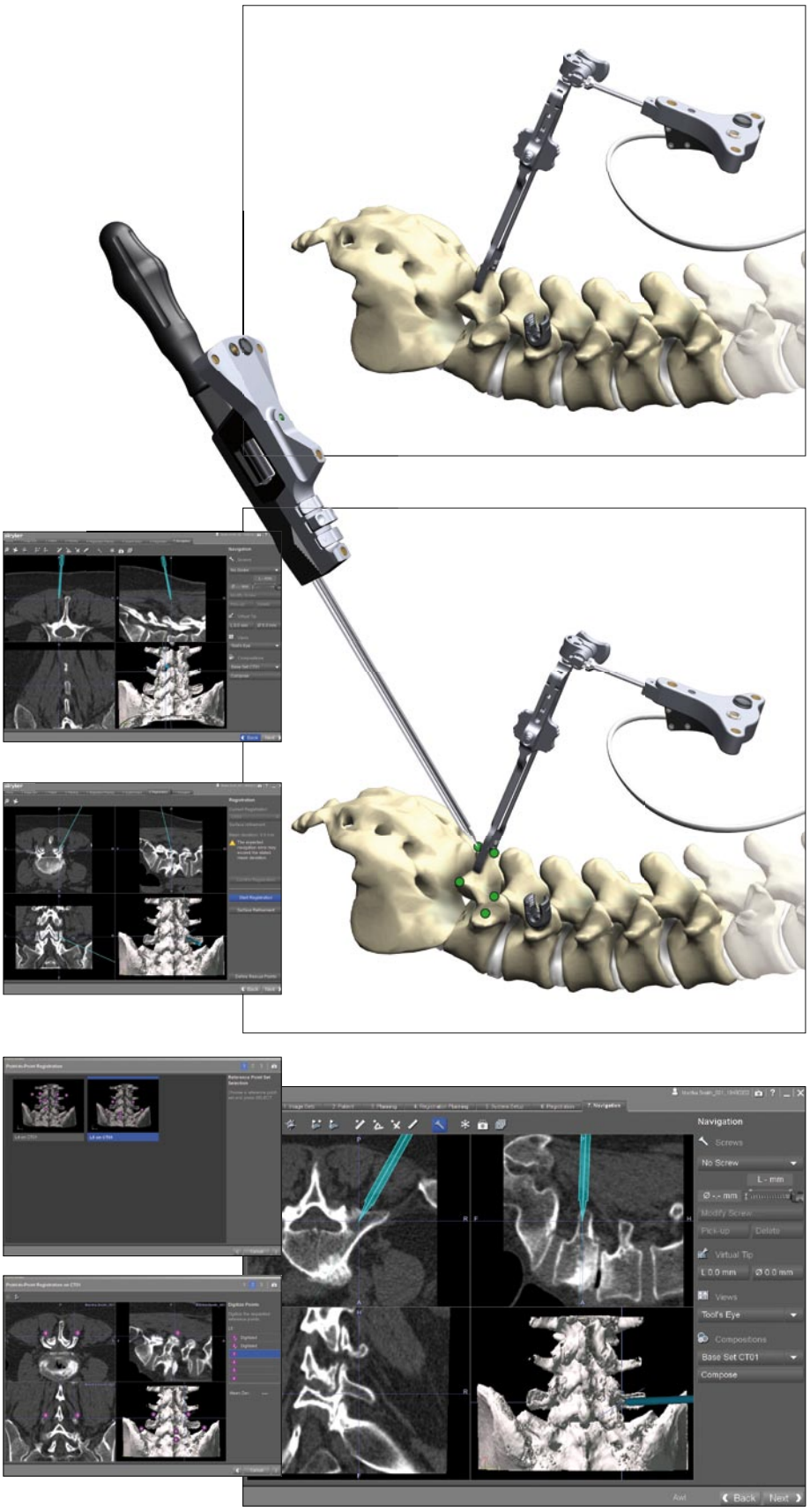
▶ Navigate the newly registered segment (not illustrated).

⚠ Caution

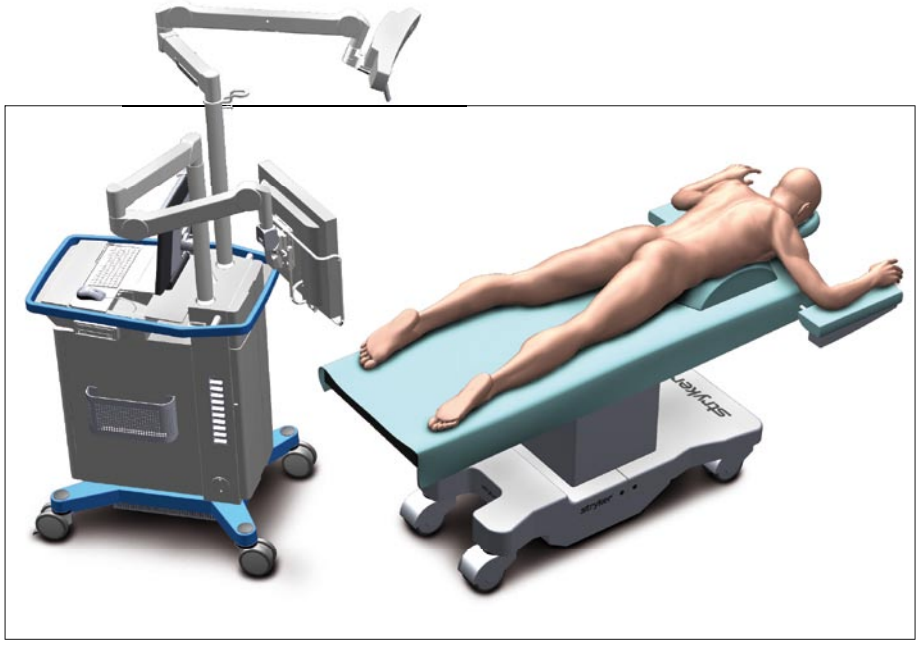
Patient position during preoperative imaging and surgery is not the same. The relative position of the individual vertebral segments on the images and during surgery may differ.

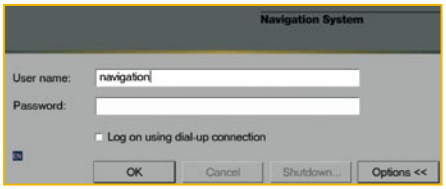
During surgery, there might be relative movement of the indivudual vertebral segments. Due to these potential deviations and movements, safe and accurate navigation of additional vertebral segments requires both:

- repositioning and fixation of the Spine Tracker onto the segment to be instrumented next and
- new registration of this segment.



11. Navigated Minimal Invasive Spine Surgery with Intraoperative 3-D Imaging





System Positioning & Start Up

For navigated pedicle screw insertion with posterior approach and patient in prone position, the system is commonly placed at foot or head of the OR table.

Depending on the situation in the OR, the approach and the type of surgery, other system positions are supported.

Independently of the system position:

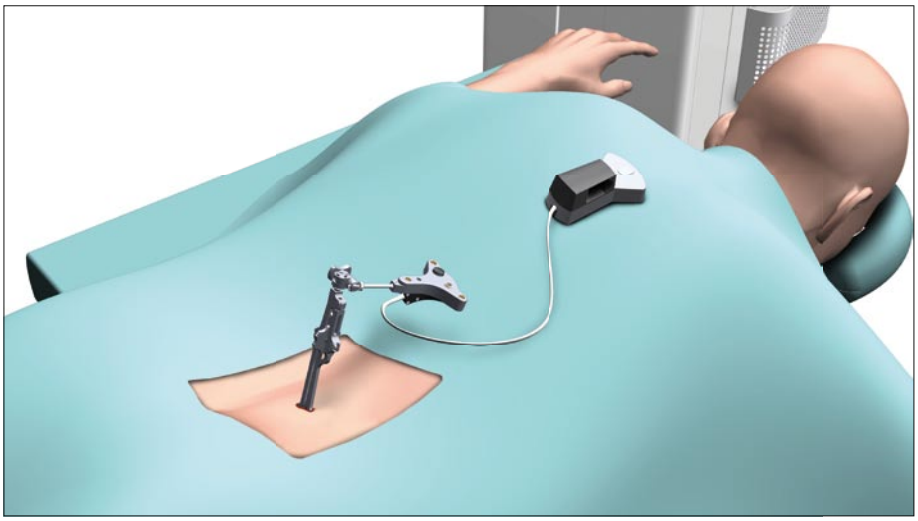
1. Position the camera 1.65 m/ 5.5 feet away, facing towards the working area.
2. Plug in the main power cable of the navigation system.
3. Press the main power button on the front panel of the navigation system.
4. Enter the **user name** (navigation) and press the **Enter** key or use the left mouse button and click the **OK** button.
5. After Application Manager start up, use the mouse to select the **SpineMap 3-D** button.

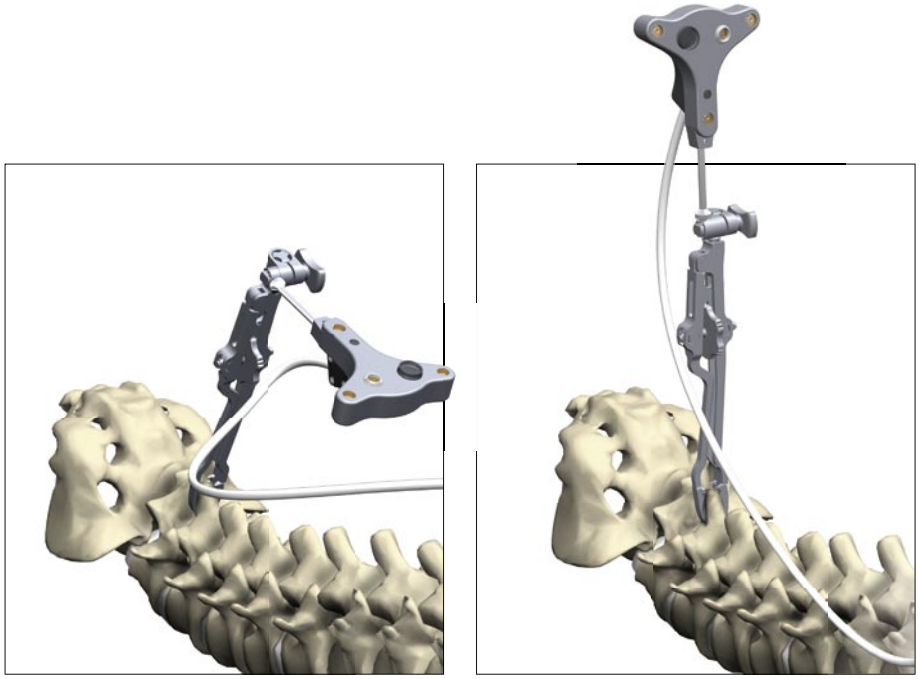
Prepare patient

For 3-D image acquisition and automatic image registration, a Spine Tracker must be fixated to the spinous process of the vertebra that will be instrumented first.

Step 1: Position patient, prepare patient and incision

1. Position and prepare the patient in accordance with the standard protocol.
2. Identify the correct level that will be instrumented first, for example, by acquiring an AP image.
3. Make a minimal invasive key hole incision above the spinous process of the identified level to enable Spine Clamp fixation.





Step 2: Fixate spine clamp and spine tracker

1. Fixate the Spine Clamp firmly onto the spinous process of the identified vertebra.
2. Attach the Spine Tracker onto the Spine Clamp and align it line of sight to the camera.
3. Verify the stability of the connection between the Spine Clamp and the spinous process again.

⚠ **Caution:**

The metal of the Spine Clamp and Spine Tracker may compromise the intraoperative 3-D C-arm image quality.

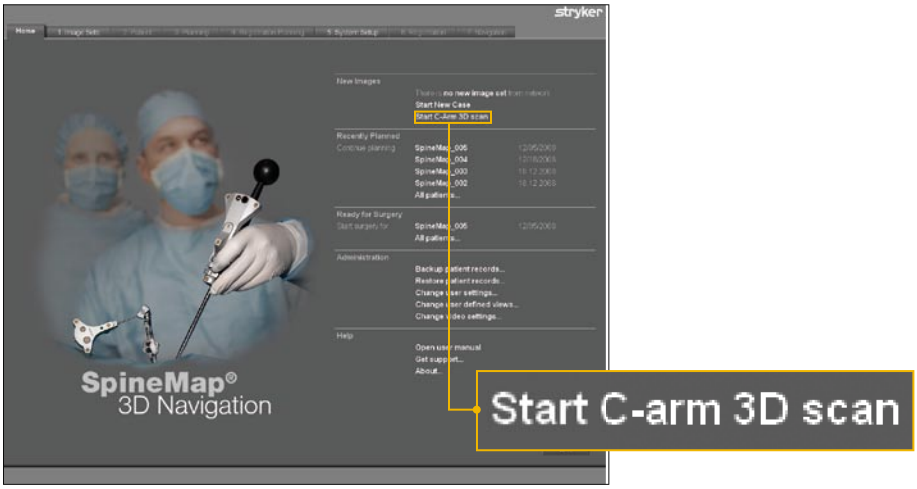
When attaching and aligning the Spine Clamp and the Spine Tracker. Ensure that they do not block the intraoperative x-ray beam imaging the pedicles to be treated.

If the field of view of the x-ray beam contains the entire Spine Clamp and Spine Tracker, a "tower" set up and alignment inbetween the disc space of the vertebra used for Spine Clamp fixation and the inferior neighboring vertebra might be appropriate.

Start up C-Arm 3-D scan

Stryker SpineMap 3-D navigation software supports automatic registration of intraoperative 3-D images of the following C-Arms:

- Siemens Siremobil® Iso-C 3-D
- Siemens Arcadis® Orbic 3-D
- Ziehm Vision Vario 3-D
- Ziehm Vision Vario FD 3-D



Step 1: Initiate 3-D scan

To start navigation with intraoperative 3-D C-Arm images:

▶ Select the **Start C-Arm 3-D scan** link from the Home page.

Step 2: Select 3-D C-Arm

▶ Select the C-Arm manufacturer: **Siemens** or **Ziehm**.

Note

Step 2 is skipped by the software if the Navigated 3-D scan option is selected on the C-Arm's control panel. With this setting, the C-Arm type is detected automatically by the software.

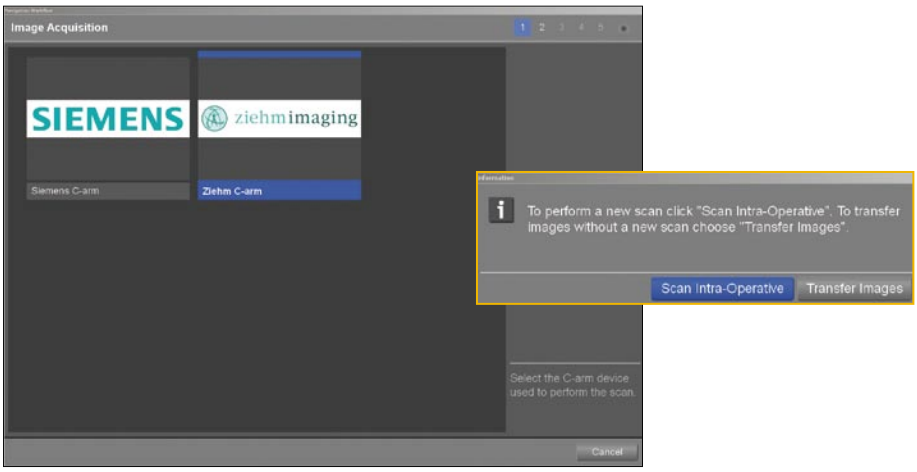
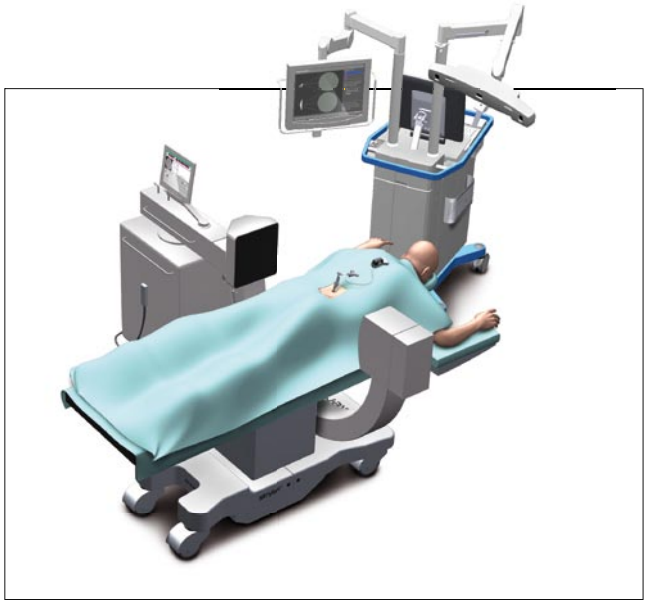


Image Acquisition
SIEMENS
ziehm imaging
Siemens C-arm
Ziehm C-arm
To perform a new scan click "Scan Intra-Operative". To transfer images without a new scan choose "Transfer Images".
Scan Intra-Operative
Transfer Images
Select the C-arm device used to perform the scan.
Cancel

Step 3: Confirm 3-D scan

▶ Select **Scan Intra-operative** to initiate intraoperative 3-D C-Arm image acquisition.

Related chapter:
6. Registration Planning, page 41.



Step 4: Prepare C-Arm

1. Position the C-Arm.
2. Connect the C-Arm to the network receptacle of the Stryker Navigation System by using an Ethernet crossover cable.

For Siemens C-Arms:

- Attach a C-Arm Tracker onto the C-Arm.

3. Prepare and drape the C-Arm.

Initialize tool

Intraoperative 3-D imaging and automatic registration require the initialization of sterile tools.

Following tools are recommended:

- Patient tracker
- VCD
- Small Pointer

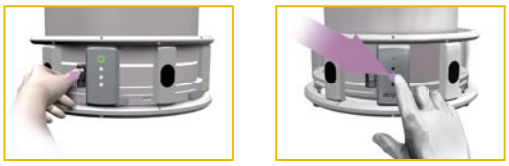
Step 1: Initialize patient tracker, VCD and pointer

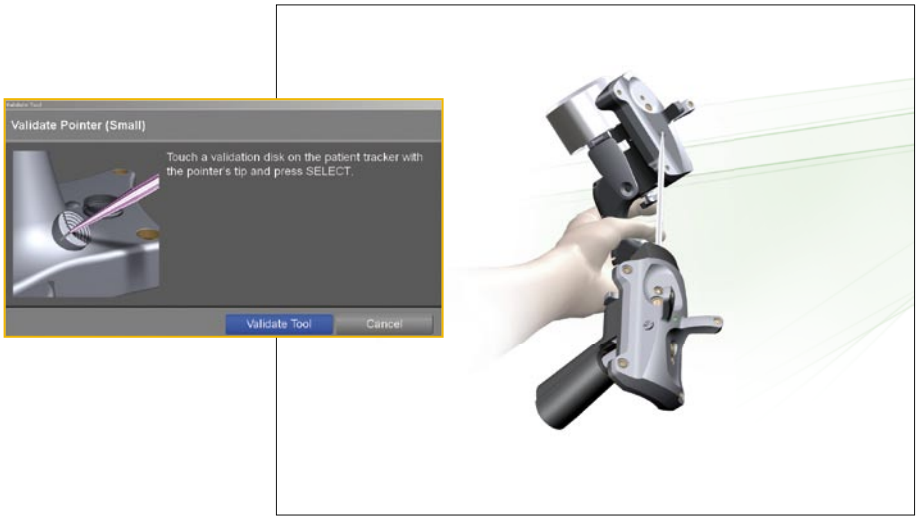
1. Load a sterile battery into the battery housing of the patient tracker.
2. Make sure that the LEDs of the patient tracker face towards the camera and press and hold the **SELECT** button for three seconds on the battery housing to initialize.
3. Repeat battery insertion and tool initialization for the sterile VCD and the sterile Pointer.

Note

The initialization of any tool is confirmed by an audible chime and a check mark in front of the software button.

For a Siemens 3-D C-Arm, a C-Arm Tracker has also to be initialized.




Validate Pointer (Small)
Touch a validation disk on the patient tracker with the pointer's tip and press SELECT.
Validate Tool
Cancel

Step 2: Validate pointer

Upon initialization of the pointer, the **Validate Tool** window appears on the screen.

- Touch the center of one of the VCD's or PCD's validation disks with the tip of the pointer and press **SELECT** on the pointer to confirm.

Acquire Ziehm 3-D C-Arm image

Step 1: Position C-Arm

1. Bring the C-Arm into position for image acquisition.
2. Follow the instructions on the C-Arm control panel and perform a collision check for the complete rotation of the C-Arm.

Note

The collision check is mandatory and requested by the 3-D workflow of the C-Arm.

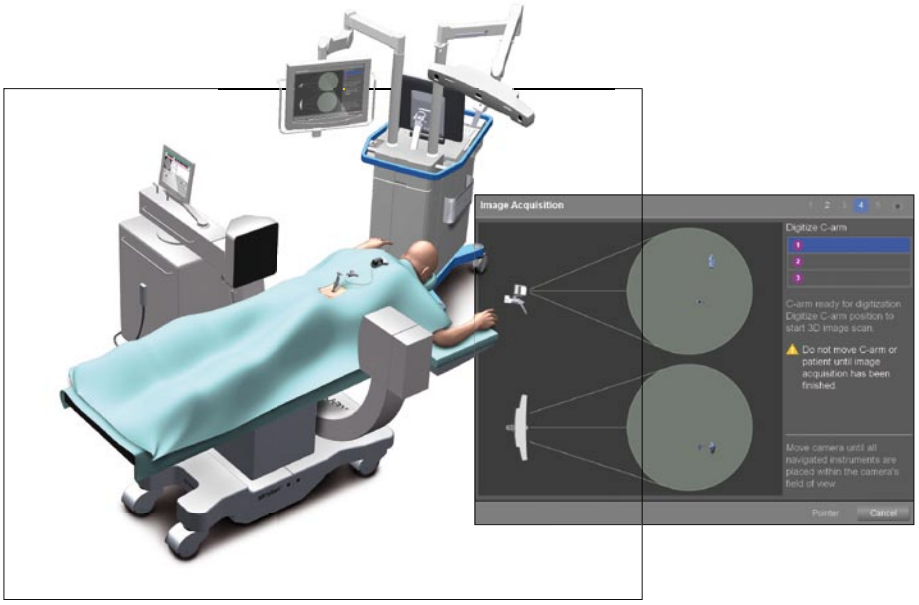


Image Acquisition
Digitize C-arm
C-arm ready for digitization
Digitize C-arm position to start 3D image scan
Do not move C-arm or patient until image acquisition has been finished
Move camera until all navigated instruments are placed within the camera's field of view
Pointer
Cancel

Step 2: Align camera

- Align the camera in such a way that the patient tracker is visible and that the C-Arm's image intensifier is within the camera's working space.

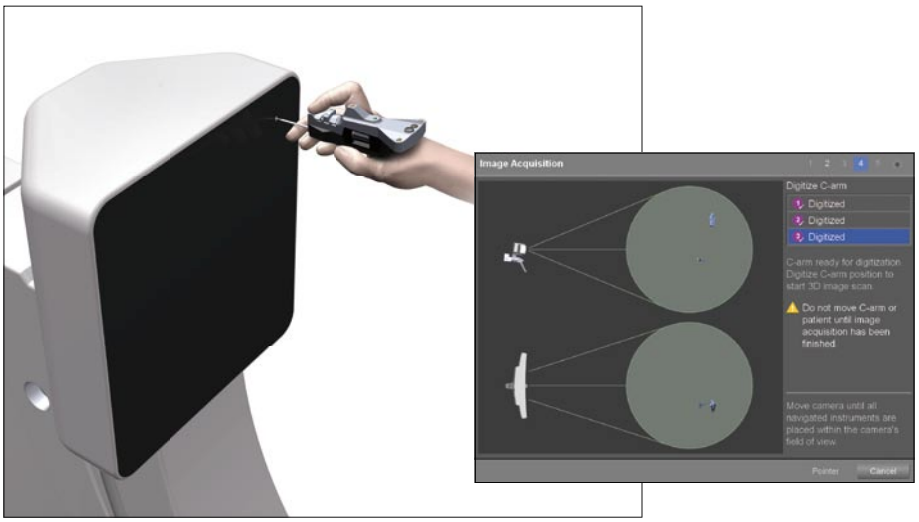


Image Acquisition
Digitize C-arm
Digitized
Digitized
Digitized
C-arm ready for digitization
Digitize C-arm position to start 3D image scan
Do not move C-arm or patient until image acquisition has been finished
Move camera until all navigated instruments are placed within the camera's field of view
Pointer
Cancel

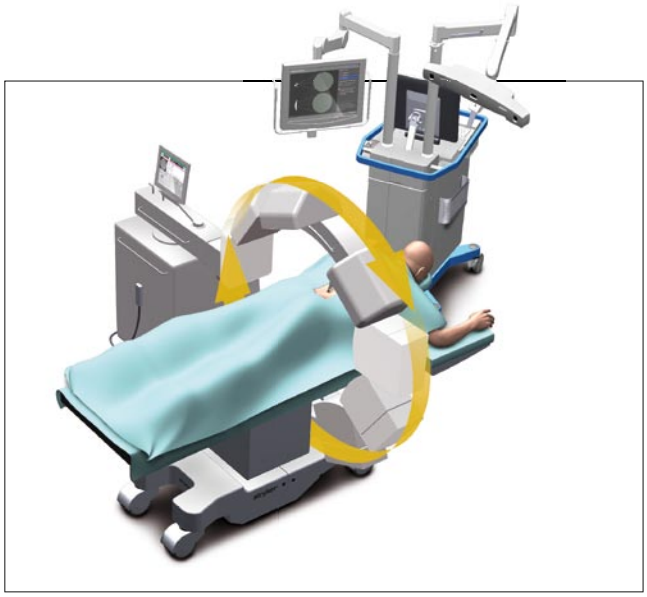
Step 3: Digitize C-Arm

Before starting:

- Ensure that the patient does not move during C-Arm digitization and image acquisition.

On the image intensifier there are three marked inserts to be digitized.

1. Using the pointer, touch the center of a marked insert and press **SELECT** on the pointer to record. Make sure not to puncture the C-Arm drape.
2. Digitize the remaining marked inserts.



Note

The digitization accuracy is displayed on the C-Arm's control panel. If the digitization accuracy is within the accepted tolerance, the system is ready for image acquisition. Acceptable digitization accuracy values are: ≤ 0.5 mm.

Step 4: Acquire image

- Start and complete the scan without interruption.

Caution

Do not move the camera or C-Arm during image acquisition.

For accurate C-Arm digitization and uncompromised image quality, patient movement has to be avoided during C-Arm digitization and image acquisition. In certain cases it might be appropriate to control patient movement by initiating a brief non-ventilated phase for the time of C-Arm digitization and image acquisition.

It is the responsibility of the surgeon to consider the particular conditions of the patient and to decide whether such actions are necessary, appropriate and safe.

Step 5: Transfer and register images

For Ziehm 3-D C-Arms, the images are transferred automatically to the navigation system as soon as the scan is complete.

The images are registered automatically. After image transfer, the Confirmation dialog starts.

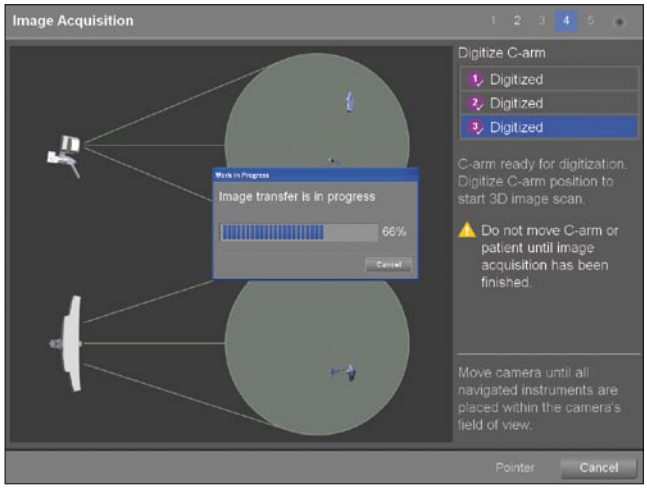


Image Acquisition
Digitize C-arm
Digitized
Digitized
Digitized
C-arm ready for digitization. Digitize C-arm position to start 3D image scan.
Do not move C-arm or patient until image acquisition has been finished.
Image transfer is in progress
66%
Move camera until all navigated instruments are placed within the camera's field of view.
Pointer
Cancel

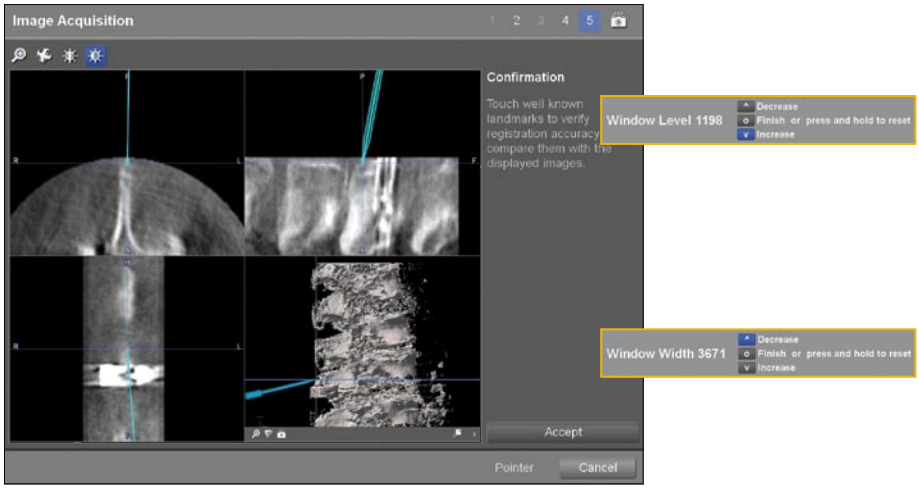
Step 6: Adjust window level/ width (optional)

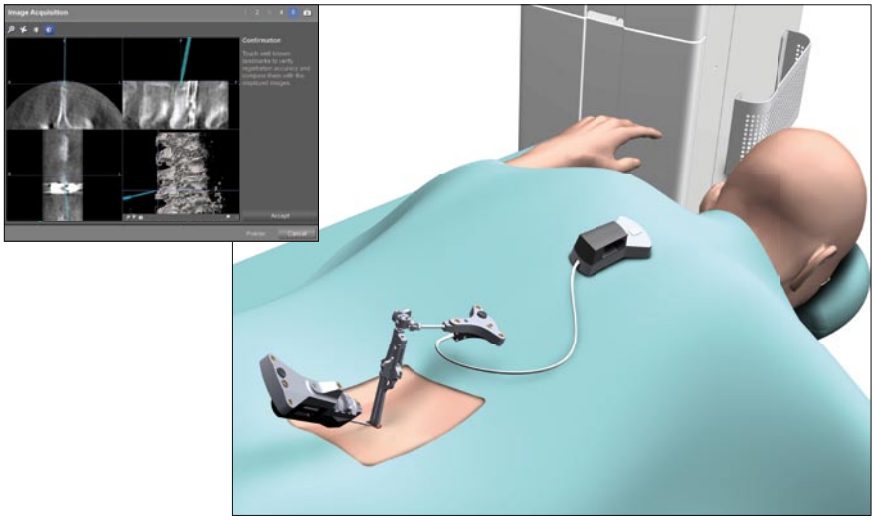
If required:

- Highlight and select the icon for changing the window level of the 3-D image while touching the patient's anatomy with the pointer.
- Highlight and select the icon for changing the window width of the 3-D image while touching the patient's anatomy with the pointer.

Note

To adjust window level/width is also possible by using the right mouse button and move the cursor up/down or left/right.





Step 7: Confirm image

To verify the registration accuracy:

1. Touch accessible bony landmarks with the pointer's tip.
2. Compare the actual tip location with the reported location on the images.

If the accuracy is satisfactory:

- Highlight and select the **Accept** button and proceed.

⚠ Caution

Always confirm registration accuracy by using multiple landmark tests. The surgeon must be comfortable with the accuracy before proceeding.

Acquire Siemens 3-D C-arm image

Step 1: Position C-arm

1. Bring the C-arm into position for image acquisition.
2. Follow the instructions on the C-arm control panel and perform a collision check for the complete rotation of the C-arm.

Note

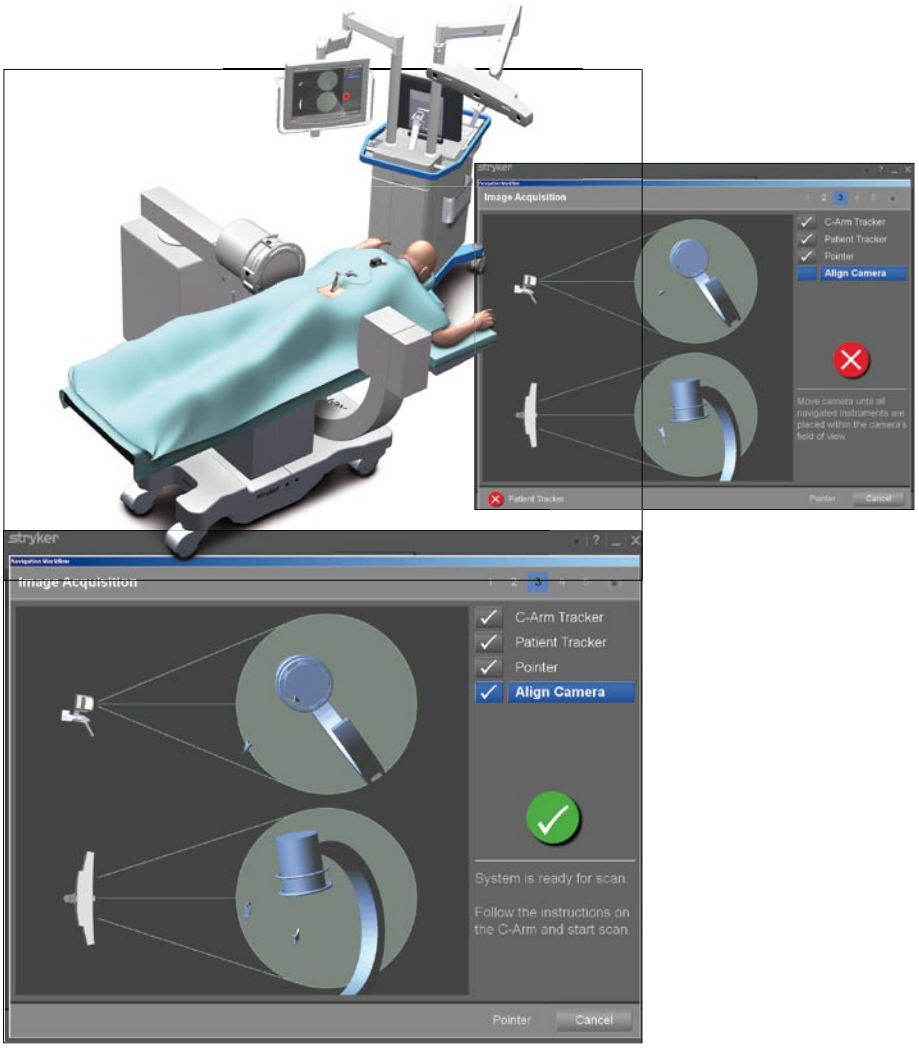
The collision check is mandatory and requested by the 3-D workflow of the C-arm.

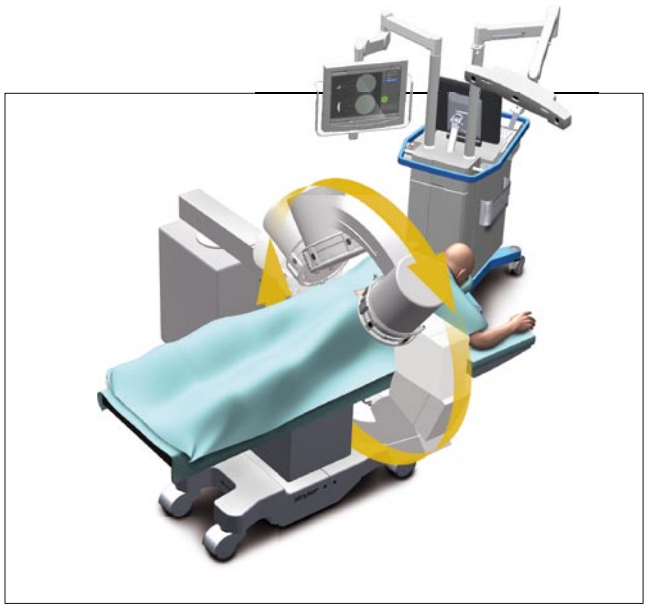
Step 2: Align camera

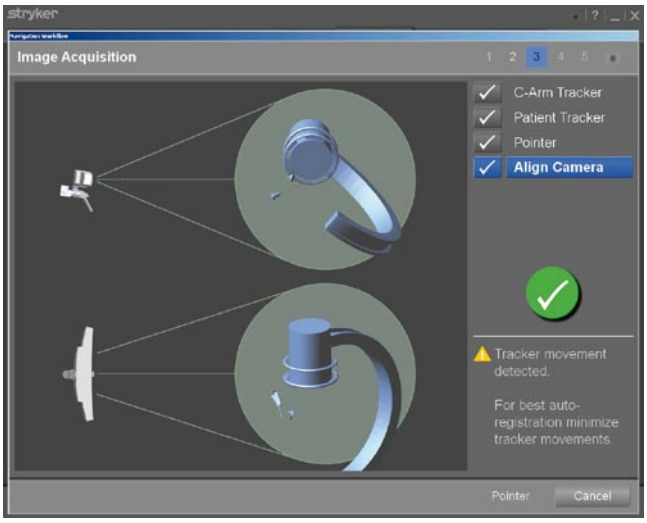
1. Align the camera in such a way that the patient tracker and C-arm tracker are visible and within the camera's working space.
2. Assure that the patient tracker and C-arm Tracker do not move.

Note

If patient tracker and C-arm Tracker are visible and in a stable position, the green light indicates that the system is ready for image acquisition.







Step 3: Acquire image

Before starting:

- Assure that the patient does not move during imaging.

Note

The scan should be completed without interruption. Incomplete scans cannot be used for navigation.

⚠ Caution

Do not move the camera or C-arm during image acquisition.

For uncompromised image quality, patient movement has to be avoided during image acquisition. In certain cases it might be appropriate to control patient movement by initiating a brief non-ventilated phase for the time of image acquisition. It is the responsibility of the surgeon to consider the particular conditions of the patient and to decide whether such actions are necessary, appropriate and safe.

Step 4: Transfer and register image

For Siemens Arcadis® Orbic 3-D, the images are transferred automatically as soon as the scan is complete.

For Siemens Siremobil® Iso C 3-D, the scans have to be transferred manually using the C-arm's control panel.

The images are registered automatically. After image transfer, the **Confirmation** dialog starts.

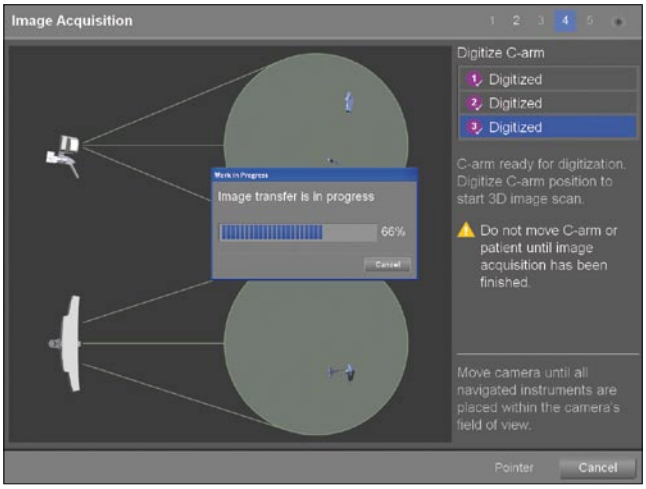
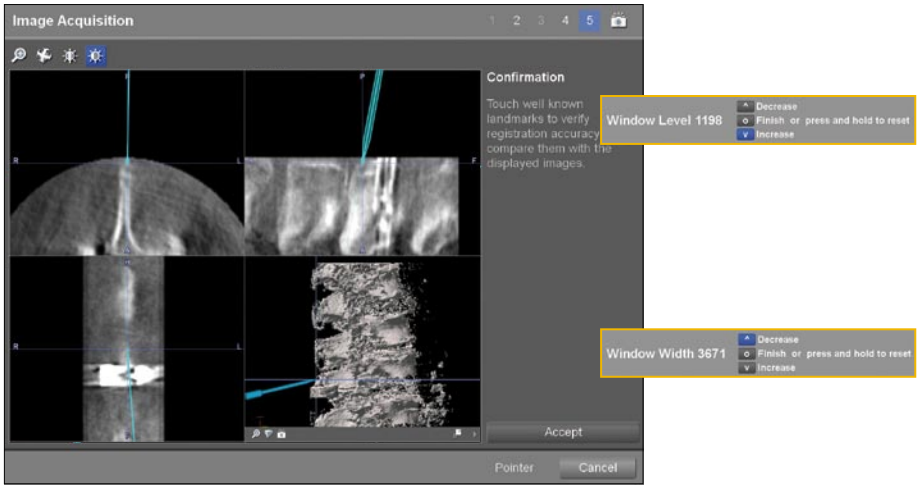


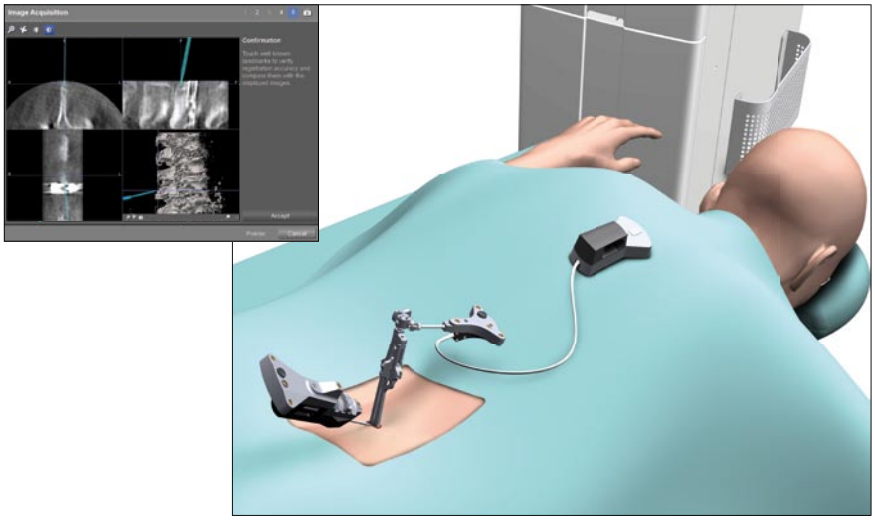
Image Acquisition
1 2 3 4 5
Digitize C-arm
1 Digitized
2 Digitized
3 Digitized
C-arm ready for digitization. Digitize C-arm position to start 3D image scan.
Do not move C-arm or patient until image acquisition has been finished.
Image transfer is in progress
66%
Move camera until all navigated instruments are placed within the camera's field of view.
Pointer
Cancel

Step 5: Adjust window level/ width (optional)

If required:

- Highlight and select the icon to change the window level of the 3-D image while touching the patient's anatomy with the pointer.
- Highlight and select the icon to change the window width of the 3-D image while touching the patient's anatomy with the pointer.





Step 6: Confirm image

To verify the registration accuracy:

1. Touch accessible bony landmarks with the pointer's tip.
2. Compare the actual tip location with the reported location on the images.

If the accuracy is satisfactory:

- Highlight and select the **Accept** button and proceed.

⚠ Caution

Always confirm registration accuracy by using multiple landmark tests. The surgeon must be comfortable with the accuracy before proceeding.

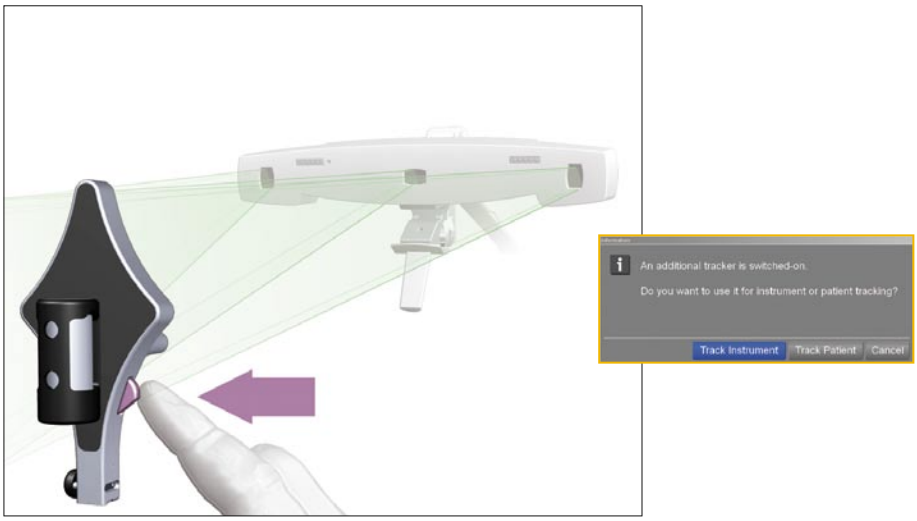
Minimal invasive pedicle screw navigation

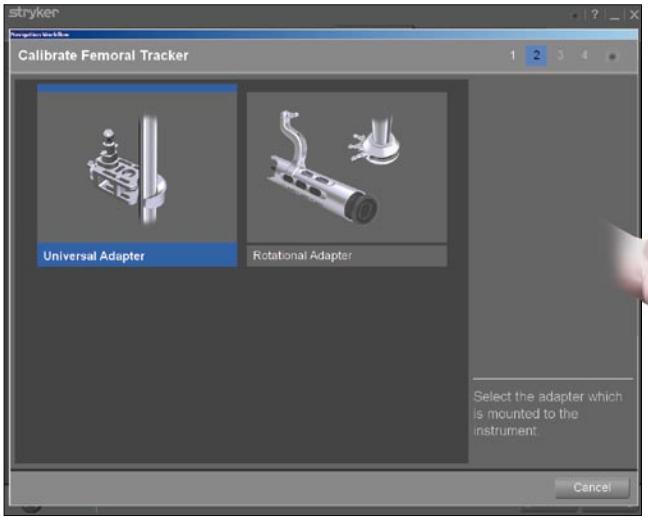
Calibrate Jam Shidi needle

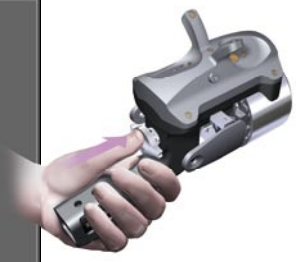
SpineMap 3-D software facilitates the integration of conventional instruments such as a spinal needle. For conventional instrument integration, a NavLock adapter, a Universal Tracker and a calibration device are required.

Step 1: Prepare tool

1. Select the required Jam Shidi needle.
2. Mount a NavLock adapter onto the Jam Shidi needle (not illustrated).
3. Attach a Universal Tracker onto the NavLock.
4. Insert a sterile battery into the Univeral Tracker (not illustrated).
5. Make sure that the Universal Tracker's LEDs face towards the camera and press and hold the tracker's **SELECT** button to initialize. Upon initialization, an information box appears.
6. Press the tracker's **SELECT** button to confirm **Track Instrument**. The **Calibrate Universal Tracker** Dialog starts.


An additional tracker is switched-on.
Do you want to use it for instrument or patient tracking?
Track Instrument
Track Patient
Cancel



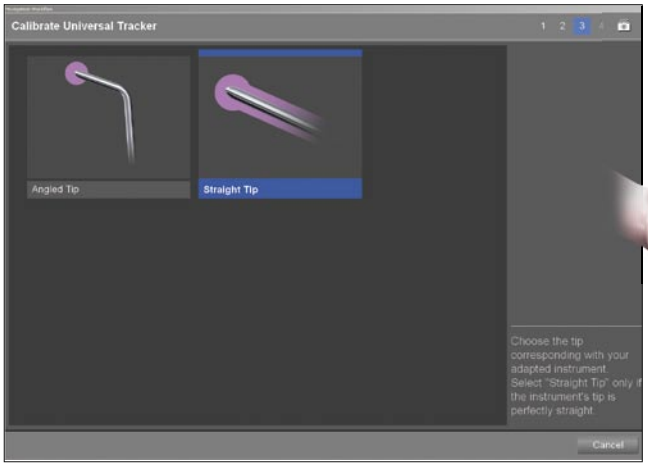


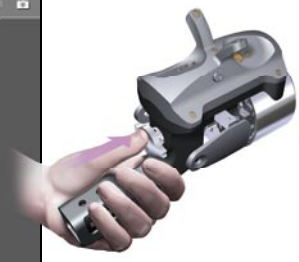
Step 2: Select adapter

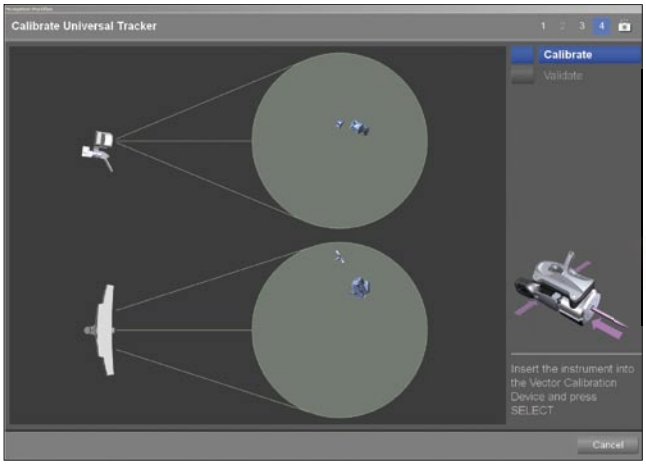
- Highlight and select **Universal Adapter** by using the VCD's **SELECT** button.

Step 3: Calibrate Jam Shidi needle (straight tip)

1. Make sure that **Straight Tip** is highlighted and press the VCD's **SELECT** button to confirm.
2. Insert the Jam Shidi needle into the opening of the VCD as indicated. Make sure the Jam Shidi needle is centered and touches the base of the device.
3. Make sure that both tools are visible and centered in the working space of the camera.
4. Press the VCD's **SELECT** button to calibrate the Jam Shidi needle (straight tip).

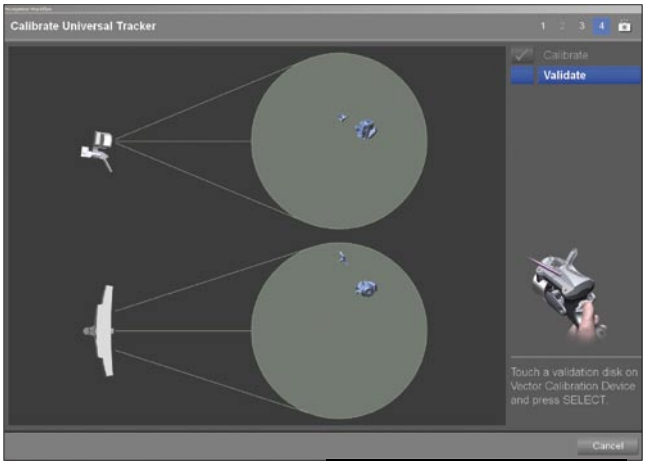

Calibrate Universal Tracker
1 2 3 4
Angled Tip
Straight Tip
Choose the tip corresponding with your adapted instrument. Select "Straight Tip" only if the instrument's tip is perfectly straight.
Cancel

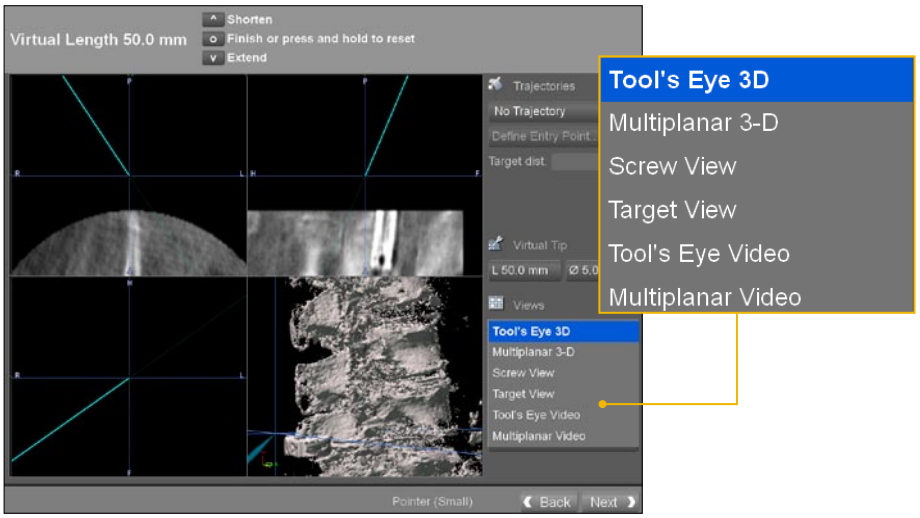




To verify the Jam Shidi needle (straight tip) calibration:

5. Touch the center of any of the VCD's validation discs with tip of the Jam Shidi needle and press the VCD's **SELECT** button to confirm.





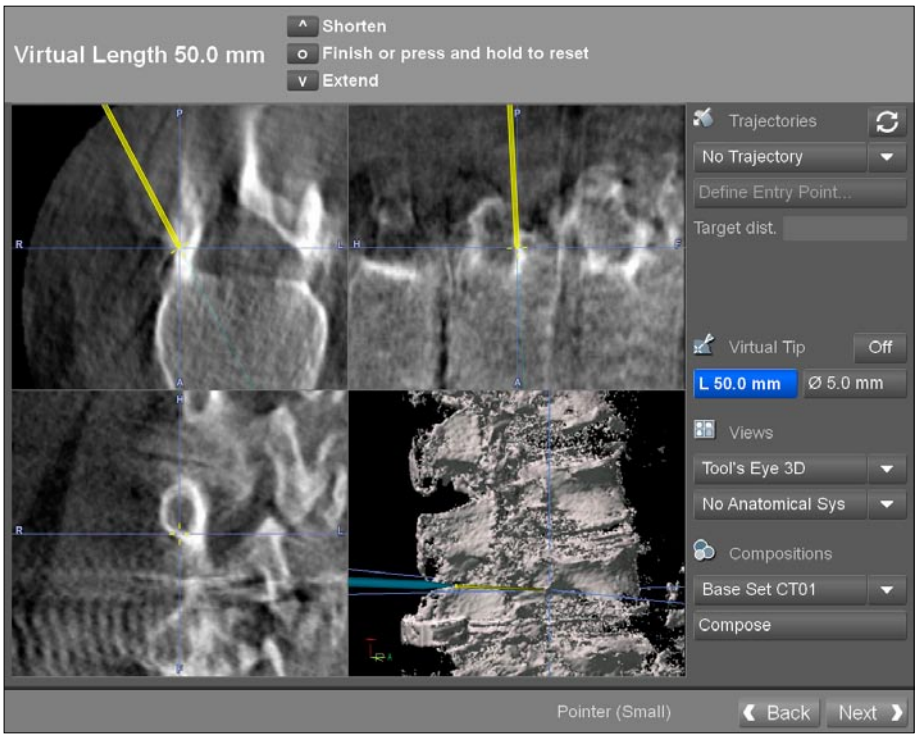
Prepare pedicle

Step 1: Select view (optional)

- Select the desired view by using the VCD's **SELECT** button.

The Tool's Eye 3-D View is commonly used for minimal invasive screw navigation.

Tool's Eye 3-D View consists of three 2-D images reconstructed with respect to the tool axis (along 0°, along 90° and perpendicular to the tool axis) and one 3-D image.



Step 2: Extense virtual tip (optional)

For navigating Jam Shidi needle insertion (Step 3), virtual tip extension might be helpful.

1. Use the VCD's **SELECT** button to select the **Virtual Tip Length** button. An adjustment bar will appear.
2. Turn the VCD's **SELECT** button down to extend the virtual tip.
3. Press the VCD's **SELECT** button to finish the virtual tip extension.

Note

Extending the virtual tip is performed in 5 mm steps, shortening is performed in 1 mm steps.

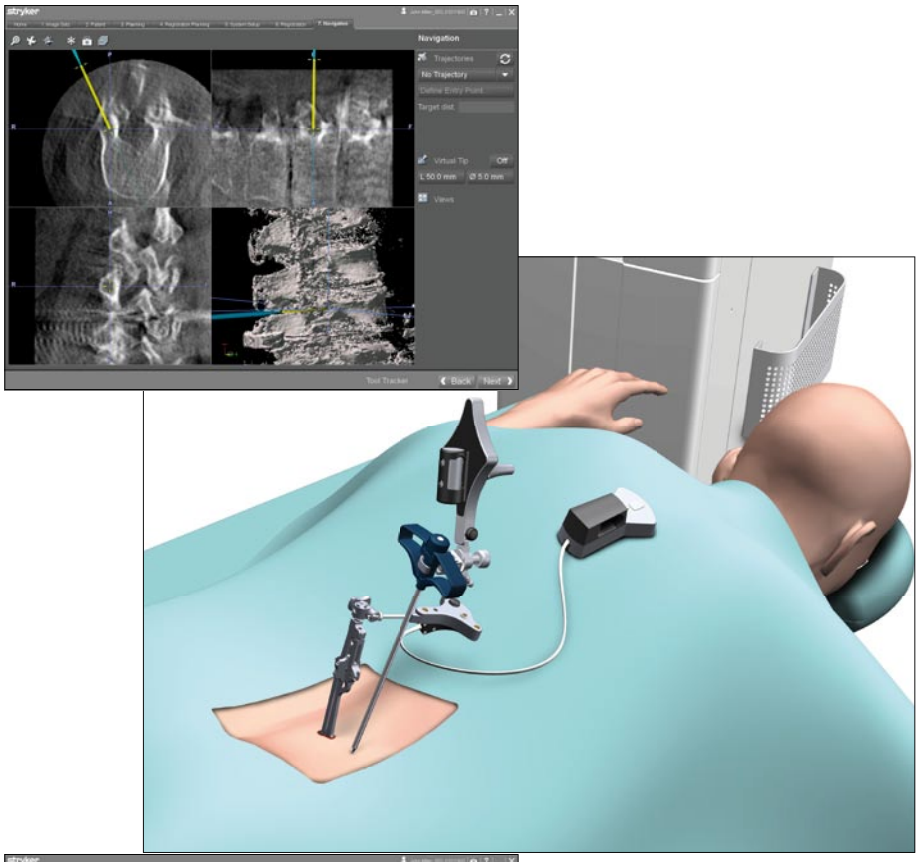
Step 3: Insert Jam Shidi needle

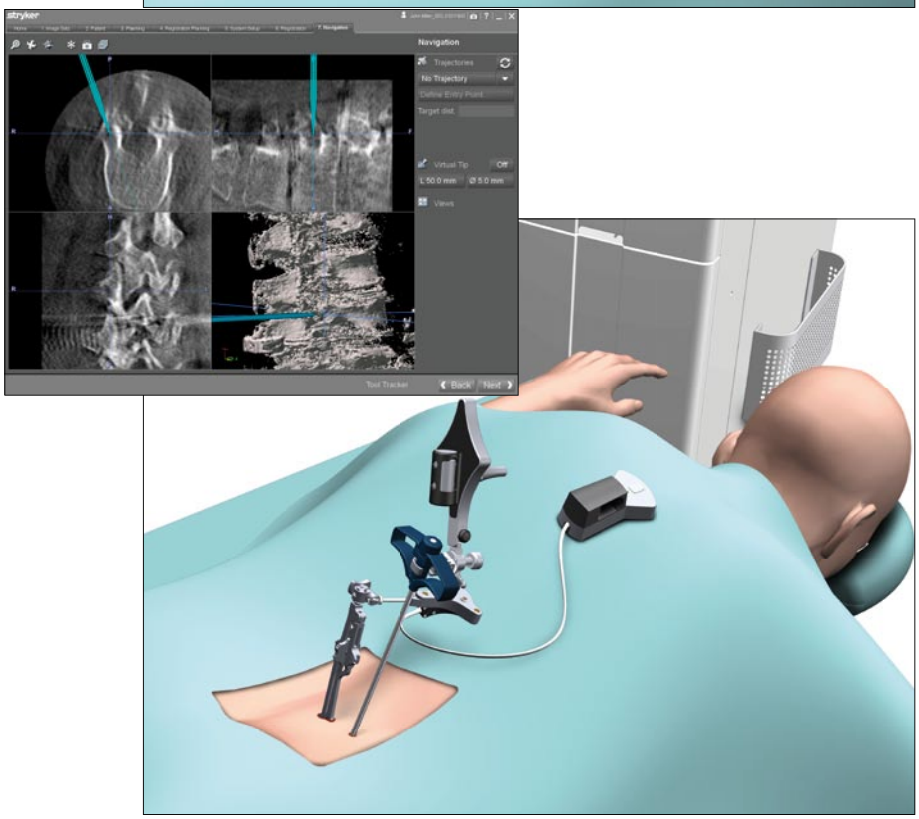
With the calibrated Jam Shidi needle, the insertion can be navigated.

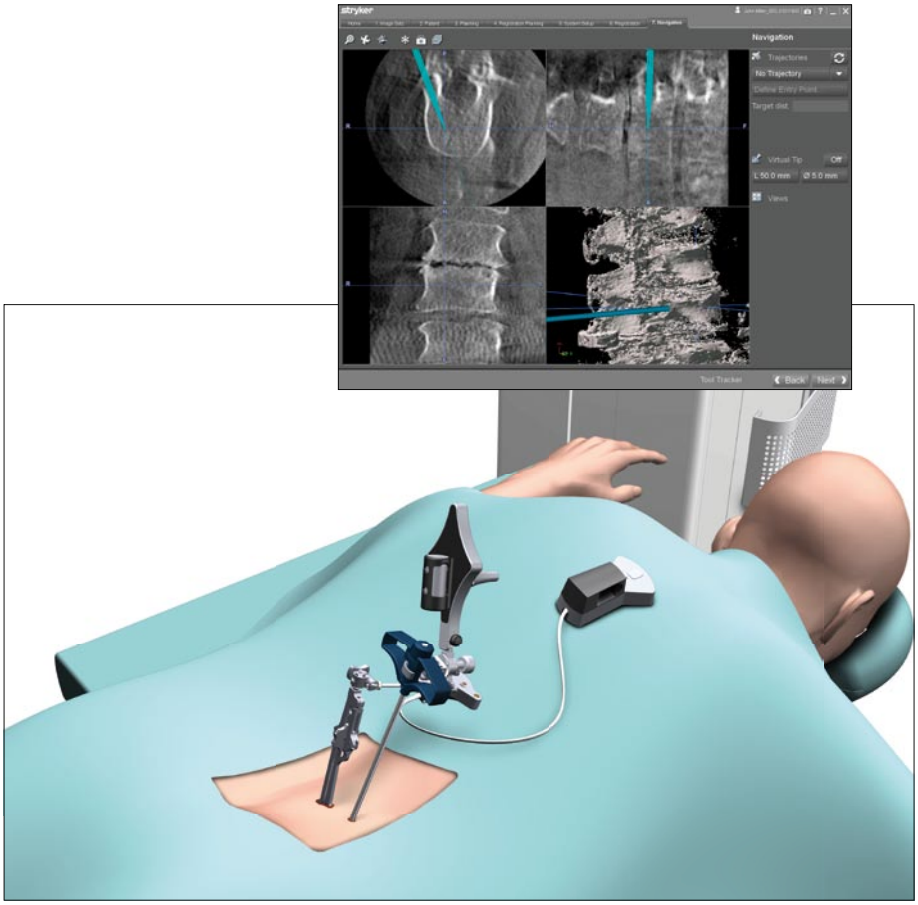
The virtually extended tip allows the user targeting of the the desired pedicle entry point and alignment and insertion of the Jam Shidi needle in accordance with the desired screw trajectory.

Step 4: Navigate entry point

After the Jam Shidi needle is inserted, the virtual tip extension can be reset and the pedicle entry point can be prepared by using the navigation control.







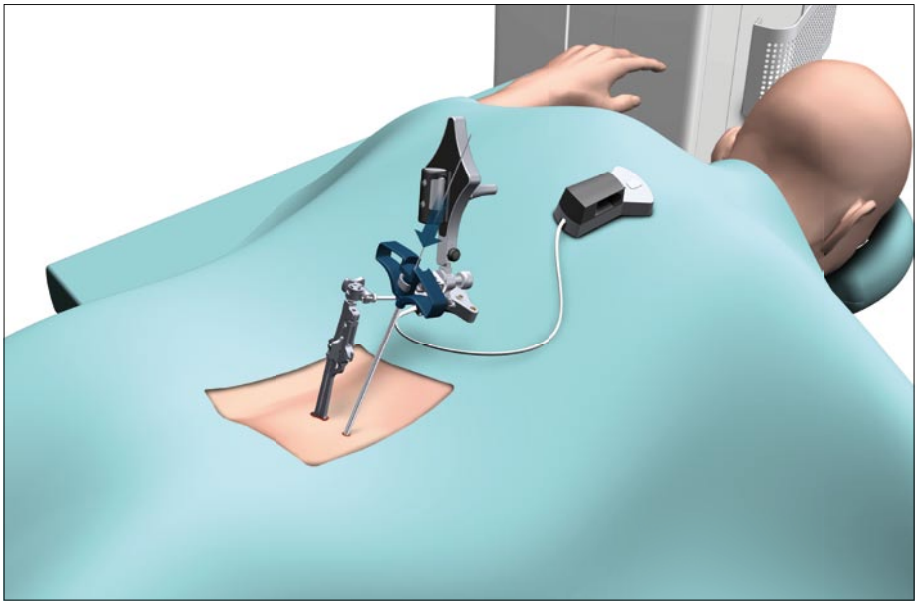
Step 5: Advance Jam Shidi needle

After entry point preparation, the Jam Shidi needle may be advanced partially through the pedicle by using navigation control.

Step 6: Insert K-Wire

The inner trocar of the Jam Shidi needle can be removed and a K-wire can be inserted into the pedicle.

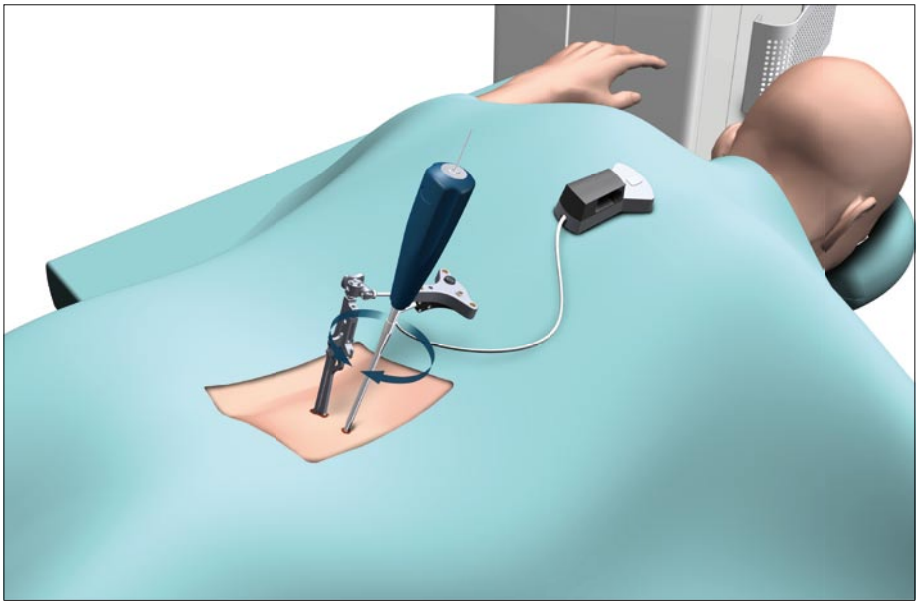
Once the K-wire is inserted, the outer shaft of the Jam Shidi needle may be removed while keeping the K-wire in place.



Step 7: Prepare pedicle pathway

The pedicle pathway can be prepared by first placing a cannulated awl over the K-wire and twisting the awl into the pedicle.

If necessary, a cannulated tap can be used in the same manner to prepare the pedicle screw canal.



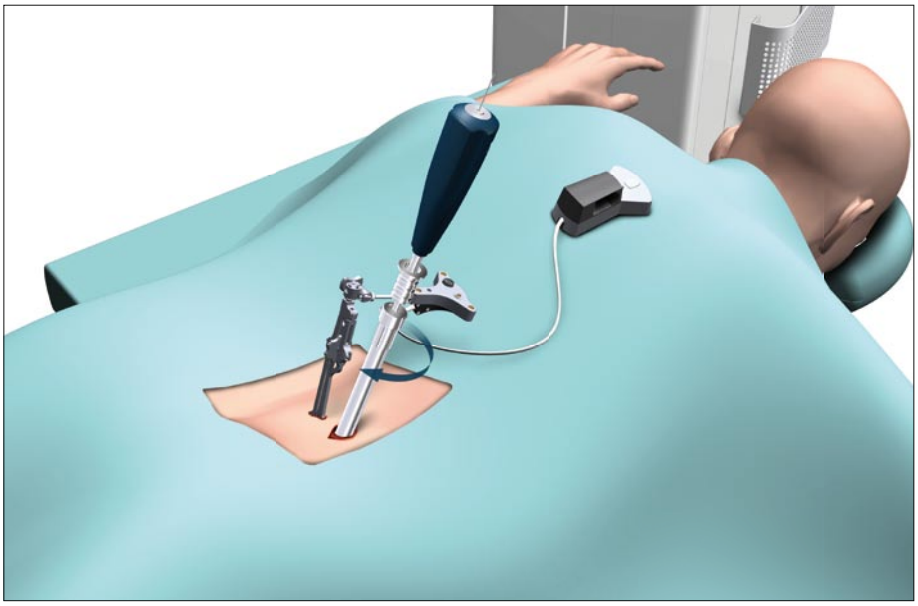
Step 8: Insert screw

After pedicle pathway preparation and the screw length and diameter determination, a cannulated pedicle screw driver with screw can be placed over the K-wire and the screw can be inserted.

⚠ **Caution:**

Additional segments may only be navigated if there is a rigid connection between the Spine Tracker and the segment to be instrumented. If the connection between Spine Tracker and the instrumented segment is not rigid, navigation accuracy may be compromised.

It is recommended to verify the calibration accuracy of the adapted Jam Shidi needle between each k-wire insertion using Hot Spot validation. To perform a Hot Spot validation, touch the center of one of the VCD's validation discs with the tip of the Jam Shidi needle and press the **SELECT** button of the Universal Tracker.



12. Calibrate Conventional Instruments

Overview

SpineMap 3-D software facilitates the integration of conventional instruments:

- NavLock Adapter
- Screwdriver
- Tracker
- Universal Tracker, or
- Femur Tracker, or
- Tibia/ Pelvis Tracker
- Calibration Device
- Vector Calibration Device (VCD), or
- Point Calibration Device (PCD)

There are two different calibration methods:

- Straight Tip Calibration for tools with a straight tip
- Angle Tip Calibration for tools with an angled tip or for tools with a tip/ shaft too wide for the opening of the VCD

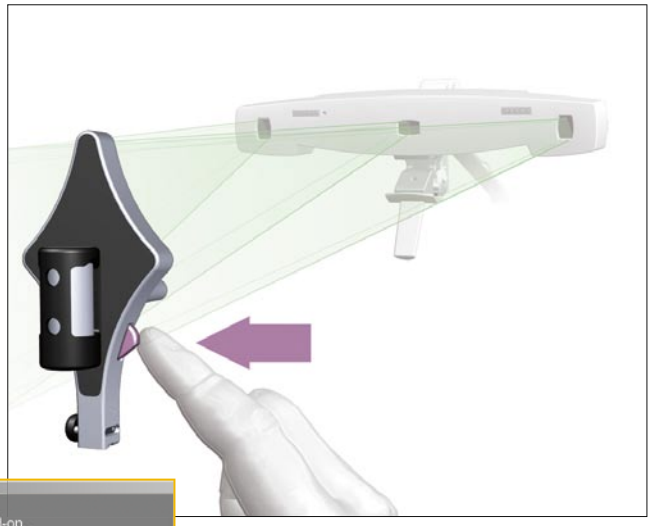
Note

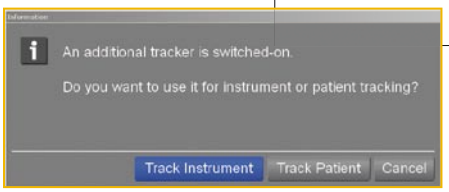
The VCD supports straight tip calibration of rigid instruments with an axis diameter varying from a minimum of 2 mm to a maximum of 15 mm. The minimal length of the straight part of the instrument's shaft to be straight-calibrated is 45 mm.

The PCD supports angle tip calibration of rigid instruments and straight tip calibration in combination with the rotational adapter.

Step 1: Prepare tools

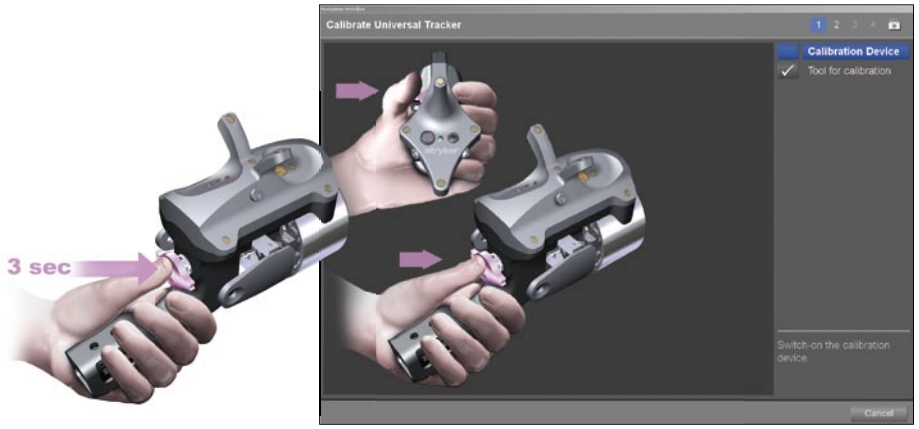
1. Select the required conventional tool.
2. Mount a NavLock adapter onto the tool.
3. Attach a tracker onto the NavLock.
4. Insert a sterile battery into the tracker (not illustrated).
5. Make sure that the tracker's LEDs face towards the camera and press **SELECT** on the tracker to initialize. Upon initialization, an information box appears.
6. Highlight and select Track Instrument. The **Calibrate Tracker** dialog starts.




An additional tracker is switched-on.
Do you want to use it for instrument or patient tracking?
Track Instrument
Track Patient
Cancel

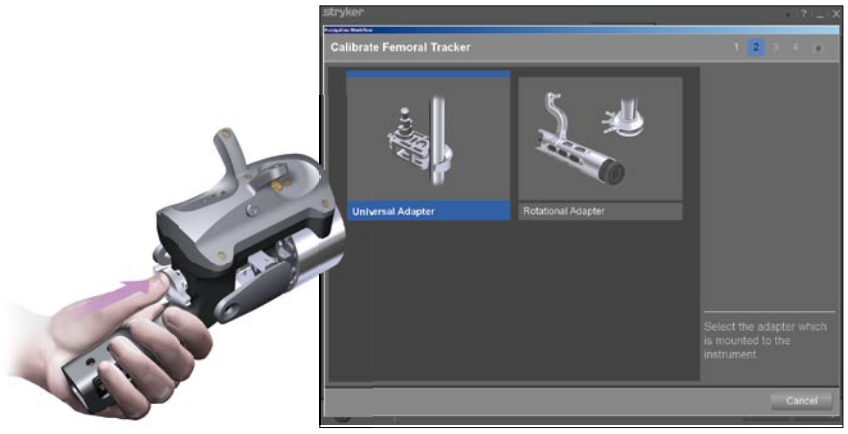
Step 2: Initialize calibration device

1. Insert a sterile battery into the VCD (not illustrated).
2. Make sure that the VCD's LEDs face toward the camera and press the **SELECT** button for three seconds on the VCD to initialize it.

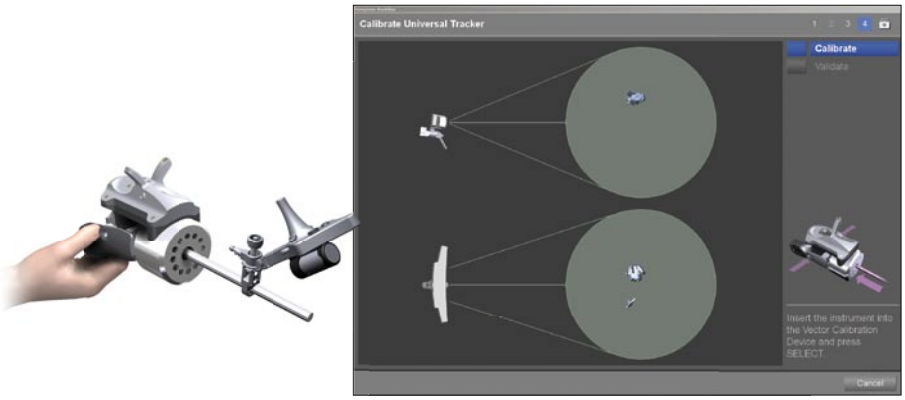


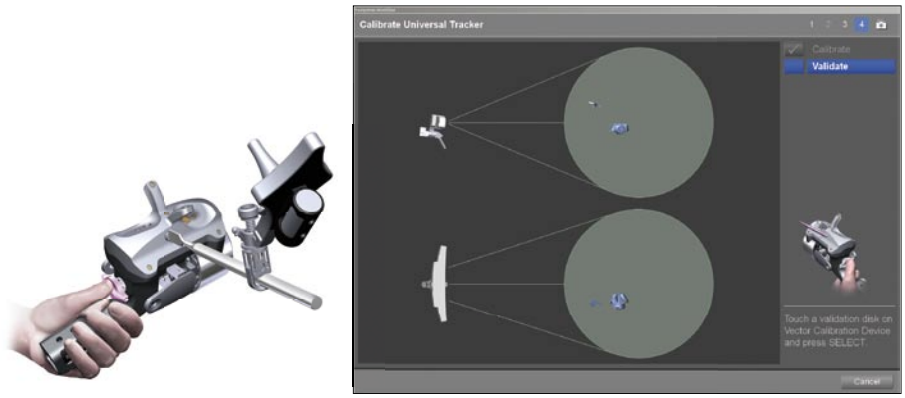
Step 3: Select adapter

- Highlight and select **Universal Adapter** by pressing **SELECT** on the VCD.



Calibrate Universal Tracker
Angled Tip
Straight Tip
Choose the tip corresponding with your adapted instrument.
Select "Straight Tip" only if the instrument's tip is perfectly straight.
Cancel





Calibration of straight tool tips

Step 4a: Select calibration method

- Highlight and select Straight Tip using **SELECT** on the VCD.

Step 5a: Straight tip calibration

1. Insert the straight tool into the opening of the VCD.
2. Make sure that the tool is centered and touches the base of the device.
3. Make sure that both the VCD and the tool are visible and centered in the working space of the camera.
4. Press **SELECT** on the VCD to calibrate the straight tool tip.

To validate the straight tool tip calibration:

- Touch the center of any of the VCD's validation discs with the tip of the tool and press **SELECT** on the VCD to confirm. Upon completion, the tool is ready for navigation.

Note

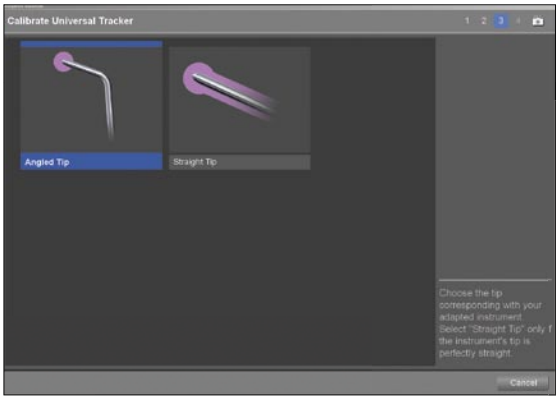
In case of a chisel tip, make sure that the chisel tip is centered in one of the validation disc's crosshair slots for validation. If the chisel tip is not centered, calibration may fail.

Calibrate angled tool tips

Step 4b: Select calibration method

For point tip calibration of (angled) tools:

- Highlight and select **Angled Tip** using **SELECT** on the VCD.

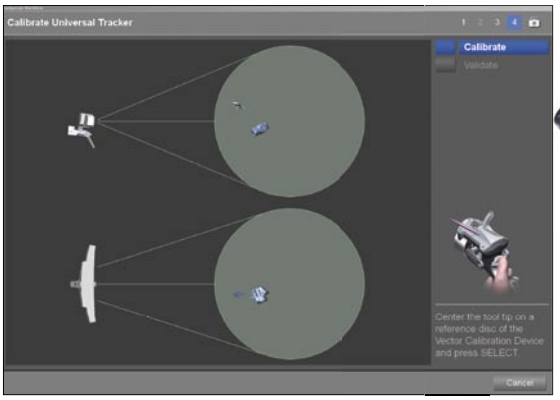

Calibrate Universal Tracker
Angled Tip
Straight Tip
Choose the tip corresponding with your adapted instrument. Select "Straight Tip" only if the instrument's tip is perfectly straight.
Cancel

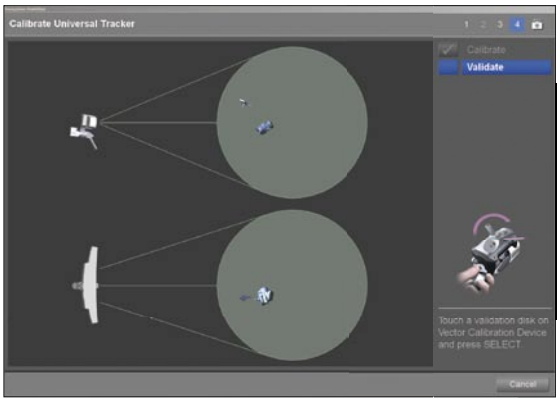
Step 5b: Calibrate point tip

1. Touch the center of one of the VCD's validation discs with the point tip of the (angled) tool.
2. Ensure that both the VCD and the tool are visible and centered in the working space of the camera.
3. Press **SELECT** on the VCD to calibrate the point tip of the (angled) tool.

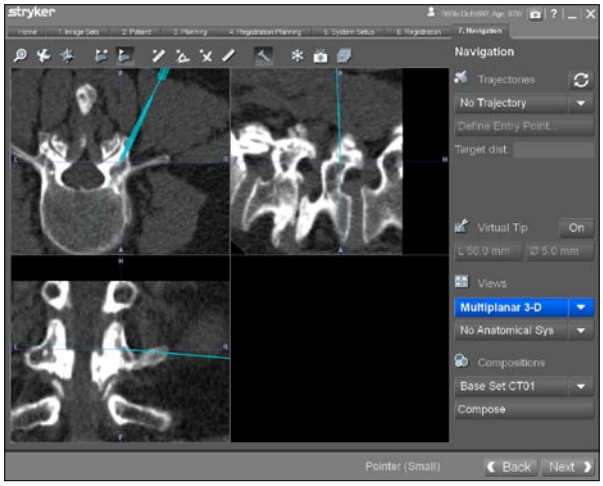
To validate the point tip calibration:

- Touch the center of the other validation disc with the point tip of the tool and press **SELECT** on the VCD to confirm. Upon completion, the tool is ready for navigation.


Calibrate Universal Tracker
Calibrate
Validate
Center the tool tip on a reference disc of the Vector Calibration Device and press SELECT.
Cancel



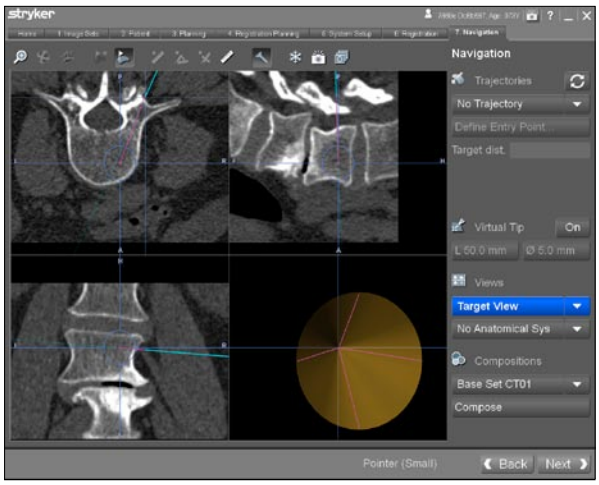
13. Navigation Views



Multiplanar views

The Multiplanar 3-D view displays an additional 3-D image with opaque or translucent surface properties.

The Multiplanar Video view displays an additional image from a defined video input device (not illustrated).



Target view

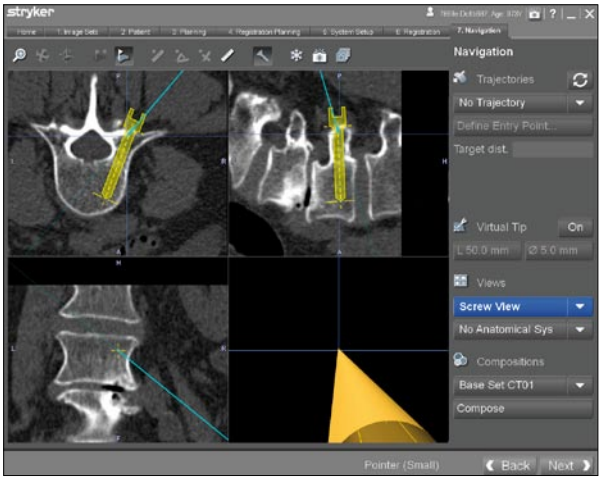
The Target view requires a planned and active trajectory with target point.

The target point position of the currently active trajectory is shown in a Multiplanar view.

The location of the tool axis is projected onto the fixed image planes.

In addition, a cone displays the position and alignment of the tool axis with respect to the target.

Screw view

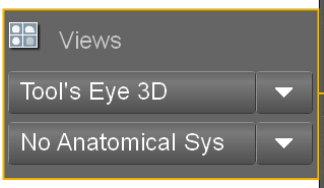


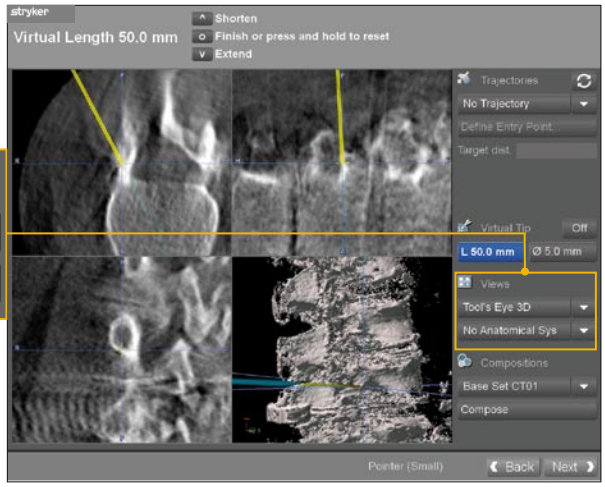
The Screw view requires a planned and active screw.

The three 2-D images of the Screw view are based on the active screw and display image planes along 0° of the screw axis, along 90° of the screw axis and an image plane perpendicular to the screw tip.

In addition, a cone displays the position and alignment of the tool axis with respect to the target.

Tool's Eye 3-D



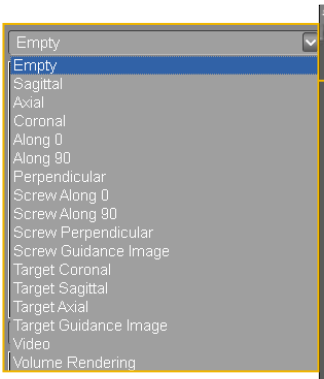


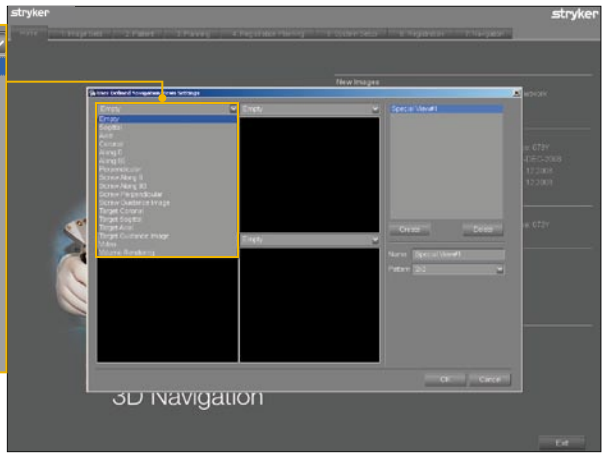
The Tool's Eye 3-D view consists of three 2-D images reconstructed with respect to the tool axis.

One 2-D image is reconstructed along 0°, the second is reconstructed along 90° and the third is reconstructed perpendicular to the tool axis.

In addition, one 3-D image with opaque or translucent surface properties is displayed.

Create user defined view

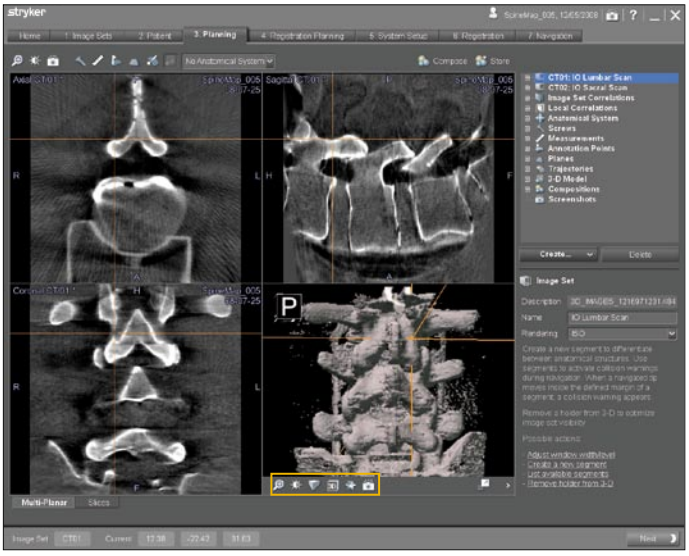




The software provides creation of user defined view.

1. Go to the Home page.
2. Click the **User defined** view settings.
3. Select view pattern, e.g. 3x2.
4. Create the desired view by using the pull-down menus of the images boxes.
5. Rename the view.

14. Additional Navigation and Documentation Tools



Navigation tools

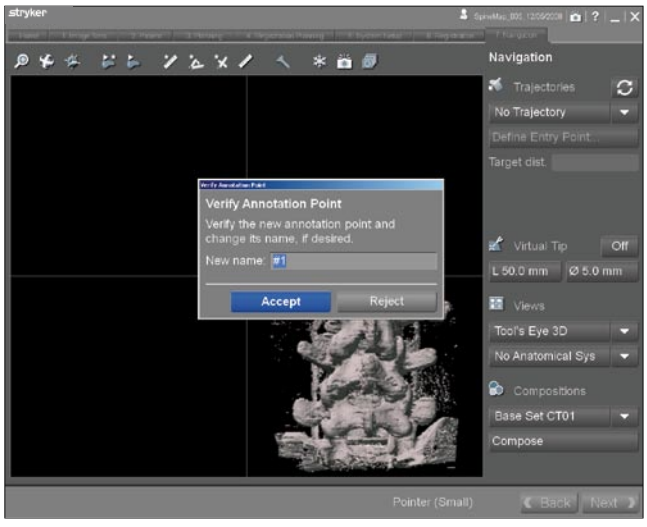
For navigation, the system offers a range of tools. The 2-D and 3-D image tools can be operated with the mouse. The tool buttons situated on top of the image box can be operated with the mouse and navigated instruments.

2-D Image Tools

3-D Image Tools

Navigation tools icon overview	
Zoom In/ Zoom Out To zoom in/out the images.	
Rotate 3-D To rotate the 3-D model to the side where the tool is pointing to.	
Cut 3-D Image To cut open the 3-D image at the current tool tip position.	
Set Annotation To set an annotation point.	
Show/ Hide Annotations To show or hide annotation.	
Show/ Hide Measurement To show or hide measurements.	
Intraoperative Distance Measurement To set an intraoperative distance measurement.	
Intraoperative Angle 3-Point Measurement To set an intraoperative angle measurement by three points.	
Intraoperative Angle 2-Line Measurement To set an intraoperative angle measurement by two lines.	
Show/ Hide Screws To show or hide screws.	
Show/Hide Plane To show or hide planes.	
Freeze Image To freeze/ unfreeze the image. A frozen image is static without the tool position being updated (not illustrated).	
Screenshot To capture the image box. The image is stored in the patient's archive directory.	
Browse Images To browse through all 2-D images of the selected image set.	

Navigation tools icon overview	
Flip To flip images.	
Rotate To rotate images.	
Rendering Setting of the rendering method iso/phong/x-ray.	
VR-Settings To select the settings for 3-D images.	



Documentation tools

Create annotation points intraoperatively

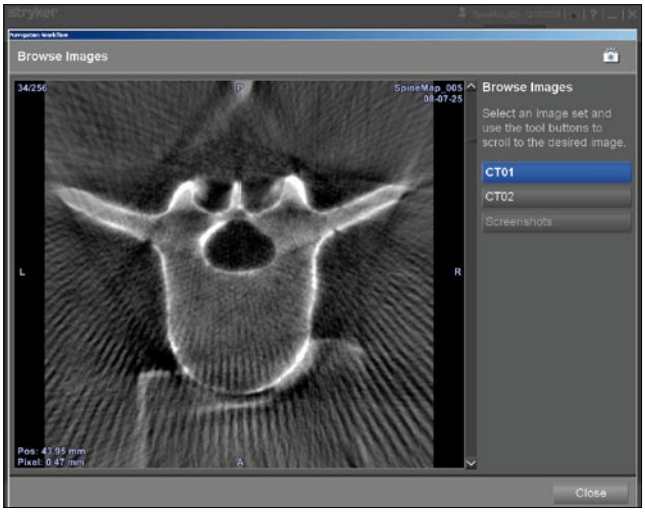
To create annotation points intraoperatively:

1. Place the instrument tip or the virtually extended tip on the point of interest.
2. Highlight and select the icon to digitize the position and to open the **Verify Annotation Point** dialog.
3. Highlight and select the **Accept** button to close the dialog.

Browse images intraoperatively

The intraoperative image browser enables an additional view of the original image set slices or on the created screenshots.

1. Highlight and select the icon to open **Browse Images** dialog.
2. Highlight and select the image set of interest.
3. Use the tool's **Up/down** buttons to scroll the original image set slices or the created screenshots.



Export screenshots

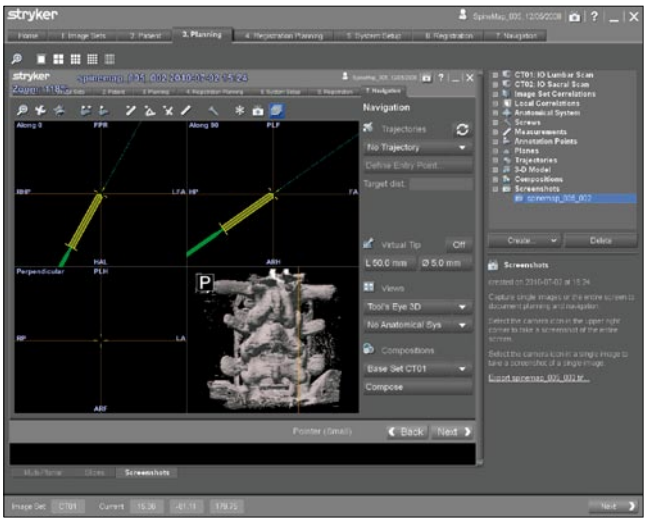
To export single screenshots, the single screenshots must be selected in the patient record tree view.

To export the created screenshots:

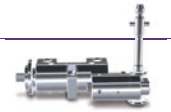
1. Select the Planning tab.
2. Double-click the Screenshot item in the patient record tree view.

Note

With the selection of **Export all screenshots** link, a Windows dialog box opens that enables the user to export all screenshots to a folder, hard drive, network drive or media such as a USB memory stick.



15. Part List

		Anchoring devices
	6002-020-000	Percutaneous Spine Clamp, Short
	6002-021-000	Percutnaeous Spine Clamp, Long
	6002-014-000	Short Spine Clamp, 4 inch
	6002-016-000	Long Spine Clamp 6 inch
	6002-017-012	Revision Pin, 12 mm
	6002-017-018	Revision Pin, 18 mm
	6007-003-000	OrthoLock Anchoring device
	6007-10x-xxx	OrthoLock Ex-Pins 3*110/ 4*150
	6007-00x-xxx	Navigation Pins 3*100/ 3*150/ 4*100
		Navigation locking adapters
	6000-999-002	NavLock 2-7
	6000-999-003	NavLock 7-13
	6000-999-004	NavLock 13-20
	6000-999-005	NavLock 20-27
	6003-100-100	Screwdriver
	6002-050-000	Rotational Navigation Adapter

Software		
SpineMap 3-D Navigation Software 2.0	6002-660-000	
Navigation platform		
Navigation System II	7700-100-000	
eNlite	7700-300-000	
Remote Planning Station	7700-010-000	
Navigated tools		
Short Pointer	6000-012-000	
Awl	6002-700-000	
Pedicle Feeler	6002-300-000	
Thoracic Pedicle Feeler	6002-350-000	
Spine Tracker	6002-005-000	
Universal Tracker	6000-005-000	

		Calibration devices
	6000-008-000	Vector Calibration Device (VCD)
	6000-010-000	Pointer Calibration Device (PCD)
		Accessories
	6000-006-000	Instrument Battery

16. Index

Symbols

3-D C-Arm image ____ 73

3-D Model ____ 12, 30

3 Point Method ____ 26

A

Anatomical system ____ 13, 39

Angle-2-lines ____ 33

Angle - 2 Lines Measurement ____ 34

Angle-3-point ____ 33

Angle - 3 Point Measurement ____ 34

Angled tool tips calibration ____ 91

Angle Tip Calibration ____ 88

Annotation points ____ 35, 96

Annotation Points ____ 13

Application Manager ____ 4

Automatic adjust ____ 7

Automatic matching ____ 15, 19

Automatic segmentation ____ 22

Automatic Segmentation button ____ 21

Axis Method ____ 25

B

Bone Segmentation ____ 22

Bounding box ____ 8

C

C-Arm 3-D scan ____ 69

Composition ____ 37

Compositions ____ 13

CT image set ____ 5

D

Documentation tools ____ 96

E

Entry point ____ 58

F

Femur Tracker ____ 88

I

Image browser ____ 97

Image orientation ____ 7

Image orientation label ____ 7

Image set ____ 7

Image Set Correlations ____ 12, 14

Image Sets dialog ____ 6

Image set size ____ 8

Import 3-D Model ____ 30

Import button ____ 10

J

Jam Shidi Needle 85, 86

K

K-Wire 86

L

Landmark matching dialog 15, 20
Length 33
Length measurement 34
Local Correlation 12, 16

M

Manual matching 15, 20
Measurement 33
Measurements 13
Media 6
Memory stick 6
Minimal invasive 66
Multiplanar Views 92

N

Navigation tools 94
NavLock Adapter 88
Network 6

P

Patient data 11
Patient dialog 12
Pedicle pathway 59
Pedicle screw 64
Pedicle screw navigation 56
Plane creation method 24
Planes 12, 24
Planning dialog 12
Point Calibration Device 88
Point tip 91
Position system 45
Power button 4

R

Ram indicator 8
Registration 47

S

Screenshots 97
Screwdriver 88
Screw Oriented Tab 32
Screws 13, 31
Screw View 93
Segmentation 12, 21

Segment types _____ 21

Slices view _____ 8

Start up system _____ 46

Straight tip calibration _____ 90

T

Tap _____ 60

Target View _____ 92

Tibia/ Pelvis Tracker _____ 88

Tolerance slider _____ 23

Tool's Eye View _____ 93

Tracker _____ 88

Track Instrument _____ 89

Trajectories _____ 12, 28

Tumor/ Vasculature/
User Defined -Segmentation _____ 23

U

Universal Tracker _____ 88

USB _____ 6

User defined view _____ 93

User name _____ 4, 46

V

Vector Calibration Device _____ 88

Virtual Tip Length _____ 84

W

Window Width / Level _____ 7

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